# Overview of planned and ongoing clinical studies of vaccines for COVID-19

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## RNA vaccines

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **mRNA-1273, Moderna**<br><br>Sponsor: National institute of Allergy and Infectious diseases;<br><br>Moderna Therapeutics;<br>Lonza | NCT04283461<br><br>Phase 1 | United States, Washington | Phase 1 open label dose ranging study of the safety and immunogenicity of 2019 nCoV vaccine (mRNA1273) in healthy adults<br><br>N=120, several doses are being tested: 10 mcg, 25 mcg, 50 mcg, 100 mcg, 250 mcg | Relevant safety outcomes; 12 months follow-up | Active, not recruiting<br><br>Estimated primary completion: November 2021 | High |
| **mRNA-1273**<br><br>Sponsor:<br>ModernaTX, Inc.<br>NIAID<br>Lonza | NCT04405076<br><br>Phase 2 | United states (multiple sites) | Phase 2a, randomized, observer-blind, placebo controlled, dose-confirmation study to assess the safety, reactogenicity, and immunogenicity of 2 dose levels of mRNA-1273 SARS-COV-2 vaccine in adults 18 years of age or older.<br><br>N=600 randomized to 50 mcg mRNA-1273 or 100 mcg mRNA-1273.<br>Each participant will receive two shots<br>The randomisation is stratified by age. 300 individuals 18-54 years and 300 individuals 55+ years | 1. Solicited local and systemic adverse reactions [Time Frame: 7 days post-vacc]<br>2. Unsolicited adverse events [ Time Frame: 28 days post-vacc]<br>3. Medically-attended adverse events [Time Frame: Month 0 through Month 13]<br>4. Serious adverse events [Time Frame: Month 0 through Month 13]<br>5. Change in the measure of clinical safety laboratory values in Cohort 2 from baseline [Time Frame: Through 1 month after last vacc]<br>6. Number and percentage of participants with abnormalities in blood pressure, temp, HR or respiratory rate [Time Frame: Through 1 year after last vacc]<br>7. Number and percentage of participants with abnormalities in physical examinations [Time Frame: Through 1 year after last vaccination]<br>8. Evaluate immunogenicity of mRNA-1273 by titer of SARS-CoV-2-specific binding antibody (bAb) measured by enzyme-linked immunosorbent assay (ELISA) [Time Frame: Through 1 year after the final dose] | Active, not recruiting<br><br>Estimated Primary Completion Date: March 2021 | High |

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| **mRNA-1273**<br><br>Sponsor:<br>Moderna<br><br>Collaborators:<br>Biomedical Advanced Research and Development Authority<br>National Institute of Allergy and Infectious Diseases (NIAID) | NCT04470427<br><br>Phase 3 | Multicentre study in US | A Phase 3, Randomized, Stratified, Observer-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older<br><br>N=30,000<br>Participants will receive 1 intramuscular (IM) injection of 100 microgram (ug) mRNA-1273 or placebo on Day 1 and on Day 29. | Number of Participants with a First Occurrence of COVID-19 Starting 14 Days after Second Dose of mRNA-1273 [ Time Frame: Day 29 (second dose) up to Day 759 (2 years after second dose) ]<br>Number of Participants with Adverse Events (AEs) or Medically Attended AEs (MAAEs) Leading to Withdrawal [ Time Frame: Up to Day 759 (2 years after second dose) ]<br>Number of Participants with Solicited Local and Systemic Adverse Reactions (ARs) [ Time Frame: Up to Day 8 (7 days after first dose) and up to Day 36 (7 days after second dose) ]<br>Number of Participants with Unsolicited AEs [ Time Frame: Up to Day 57 (28 days after each dose) ] | Recruiting<br><br>Estimated Primary Completion Date: October 27, 2022 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **BNT162, BioNTech**<br><br>BioNTech mRNA vaccine<br><br>BNT162a1<br>BNT162b1<br>BNT162b2<br>BNT162c2<br><br>Pharmaceuticals GmbH<br>+<br>Pfizer Inc. | EudraCT Number: 2020-001038-36<br><br>NCT04380701<br><br>U1111-1249-4220<br><br>BNT162-01<br><br>Phase 1/2 | Germany | Phase I/II, multi-site, non-randomized, open-label trial investigating the safety and immunogenicity of four prophylactic SARS-CoV-2 RNA vaccines against COVID-2019 using different dosing regimens in healthy adults.<br><br>N=200<br><br>The trial has two parts.<br><br>Part A: a dose-finding part with four dose cohorts for each vaccine and one pre-defined and one optional dose level for a de-escalation approach.<br>- BNT162a1 (i.m., escalating dose levels) | 1. Solicited local reactions at the injection site (pain, tenderness, erythema/redness, induration/swelling) recorded up to 7±1 days after each immunization.<br><br>2. Solicited systemic reactions (nausea, vomiting, diarrhea, headache, fatigue, myalgia, arthralgia, chills, loss of appetite, malaise, and fever) recorded up to 7±1 days after each immunization.<br><br>3. The proportion of subjects with at least 1 unsolicited treatment emergent adverse event (TEAE): [ Time Frame: 21 | Recruiting;<br>Estimated Primary Completion Date: August 2020 | High |

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| | | | - BNT162b1 (i.m., escalating dose levels)<br>- BNT162b2 (i.m., escalating dose levels)<br>- BNT162c2 (i.m., single dose)<br><br>Part B: dedicated to recruit expansion cohorts with dose levels which are selected from data generated in Part A. | days following dose administration ]<br><br>4. The proportion of subjects with at least 1 unsolicited treatment emergent adverse event (TEAE): [ Time Frame: 28 days following dose administration ] | | |
| Sponsors: Jiangsu Provincial Center for Disease Prevention and Control.<br>BioNTech RNA Pharmaceuticals GmbH.<br>Shanghai Fosun Pharmaceutical Development, Inc. | ChiCTR2000034825<br><br>Phase 1/2 | China, Jiangsu | A Phase I clinical trial of novel coronavirus pneumonia (COVID-19) mRNA Vaccine (BNT162b1) in China | Adverse events up to 21 post vaccination | Study duration: From 2020-07-20 to 2020-12-31 | High |
| **BNT162b3**<br>BioNTech RNA Pharmaceuticals GmbH | NCT04537949<br><br>Phase 1/2 | Germany | A Multi-site, Phase I/II, 2-Part, Dose-Escalation Trial Investigating the Safety and Immunogenicity of a Prophylactic SARS-CoV-2 RNA Vaccine (BNT162b3) Against COVID-19 Using Different Dosing Regimens in Healthy Adults | Safety measures | Recruiting;<br>Estimated Primary Completion: September 2021 | High |
| **BNT162b**<br><br>Sponsor: Biontech<br>Collaborator: Shanghai Fosun Pharmaceutical Development Ca, Ltd | NCT04523571<br><br>Phase 1 | Jiangsu, China | Safety and Immunogenicity of SARS-CoV-2 mRNA Vaccine (BNT162b1) in Chinese Healthy Subjects: A Phase I, Randomized, Placebo-controlled, Observer-blind Study<br>N=144 | Safety measures | Recruiting;<br>Estimated Primary Completion: September 2020 | High |
| **BNT162**<br><br>BioNTech mRNA vaccine<br><br>BNT162b1<br>BNT162b2<br><br>Sponsor: Biontech SE<br>Collaborator: Pfizer | NCT04368728<br><br>Phase 1/2/3 | Argentina, Brazil, South Africa, Turkey, United States | Phase 1/2/3 observer-blinded, placebo-controlled, randomized dose-finding trial to Describe the Safety, Tolerability, Immunogenicity, and Potential Efficacy of Covid-19 RNA Vaccine Candidates Against COVID-19 in Healthy Adults<br><br>N = 29481 healthy adults in age groups: 18-55, 65-85 and 18-85.<br><br>Randomized to receive single dose of low-, medium- or high-dose or two doses of low-, medium- or high-dose of BNT162b1, BNT162b2, or placebo injection (21 arms) | Phase 1:<br>Percentage of participants reporting:<br>- Local reactions<br>- Systemic events<br>- (Serious) Adverse events<br><br>Percentage of sentinel cohort participants with grading shifts and abnormal hematology and laboratory values<br><br>Phase 2/3 study: safety measures up to 6 months post vaccination | Active, not recruiting<br><br>Estimated primary Completion Date: June 28, 2021 | High |

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| | | | | Phase 2/3 study: confirmed covid-19 from 7 days after the last dose of study intervention to the end of the study, up to 2 years | | |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **CVnCoV, CureVac**<br><br>Sponsor: Curevac, CEPI | NCT04449276<br><br>Phase 1 | Germany | A Phase 1, Partially Blind, Placebo-controlled, Dose-escalation, First-in-human, Clinical Trial to Evaluate the Safety, Reactogenicity and Immunogenicity After 1 and 2 Doses of the Investigational SARS-CoV-2 mRNA Vaccine CVnCoV Administered Intramuscularly in Healthy Adults.<br>N=168 | Safety | Recruiting;<br>Estimated primary completion: August 2021 | High |
| CVnCoV , Curevac | NCT04515147<br><br>Phase 2 | Not stated yet | A Phase 2a, Partially Observer-blind, Multicenter, Controlled, Dose-confirmation Clinical Trial to Evaluate the Safety, Reactogenicity and Immunogenicity of the Investigational SARS-CoV-2 mRNA Vaccine CVnCoV in Adults >60 Years of Age and 18 to 60 Years of Age<br>N=691 randomised to 6 microgram, 8 microgram, 4 µg double dose, hepatitis A, pneumococ | Safety, antibodies, neutralising antibodies | Not yet recruiting;<br>Estimated Primary Completion: November 9, 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **LUNAR-COV19, Arcturus Therapeutics and Duke-NUS**<br><br>(ARCT-021)<br><br>Sponsor: Arcturus Therapeutics, Inc | NCT04480957<br><br>Phase 1/2 | Singapore | A Phase 1/2 Randomised, Double Blinded, Placebo Controlled, Ascending Dose Study to Assess the Safety, Tolerability, and Immunogenicity of ARCT-021 in Healthy Adult Subjects<br>N=92 randomised to 3 different doses and 2 different dosing regimen | Incidence, severity and dose-relationship of AEs [ Time Frame: 56 days ] | Recruiting;<br><br>Estimated primary completion:<br>December 2020 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **RNA vaccine, Imperial College London**<br><br>LNP-nCoVsaRNA | https://www.imperial.ac.uk/covid-19-vaccine-trial/<br><br>ISRCTN17072692<br><br>Phase 1 | UK | A first-in-human clinical trial to assess the safety and immunogenicity of a self-amplifying ribonucleic acid (saRNA) vaccine encoding the S glycoprotein of SARS-CoV-2, the causative agent of COVID-19<br><br>3 components of the trial:<br>Open-label, non-randomised dose escalation: 15 participants age 18-45 will be in the dose-escalation component.<br><br>Randomised dose evaluation: 105 individuals aged 18-45 will be enrolled through a single centre. Participants and laboratory staff will be blind to allocation. Participants will be allocated in a 1:1:1 ratio to the three different doses based on block randomisation. They will be followed up for 52 weeks in total.<br><br>Non-randomised expanded safety evaluation: At least 200 individuals aged 18-75 will receive the highest dose (1 µg) enrolled through multiple centres. | Adverse events<br><br>Neutralising antibodies<br><br>Vaccine induced serum IgG binding antibodies | Planned to start mid June and last for 2 months<br>Interim results available end of August | High |

| **Vaccine, Sponsor** | **Study identifier/link to website** | **Location** | **Study design** | **Primary outcome** | **Status of trial** | **Importance** |
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| **People's Liberation Army (PLA) Academy of Military Sciences/Walvax Biotech.** | ChiCTR2000034112<br><br>Phase 1 | Zhejiang and Guangxi Zhuang Autonomous Region, China | A Phase I clinical trial to evaluate the safety, tolerance and preliminary immunogenicity of different doses of a SARS-CoV-2 mRNA vaccine in population aged 18-59 years and 60 years and above<br><br>N=168 | IgG antibody, Neutralizing antibody, cellular immunity | From 2020-06-25 To 2021-12-31 | High |

## DNA vaccines

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **INO-4800, Inovio**<br>Device: CELLECTRA® 2000<br><br>Sponsor: Inovio Pharmaceuticals | NCT04336410<br><br>Phase 1 | United States, Kentucky, Missouri and Pennsylvania | Phase 1 Open-label Study to Evaluate the Safety, Tolerability and Immunogenicity of INO-4800 for a Novel Coronavirus (COVID-19) in Healthy Volunteers<br><br>N=120<br>Two different doses will be tested | Safety and efficacy<br>Time frame week: 52 | Active, not recruiting;<br>Estimated Primary Completion:<br>July 2021 | High |
| INO-4800<br><br>Sponsor: International Vaccine Institute | NCT04447781<br><br>Phase 1/2 | Not stated yet | A Phase I/IIa, Dose-Ranging Trial to Evaluate Safety, Tolerability and Immunogenicity of INO-4800<br><br>N=160 participants | Safety and efficacy<br>Time frame week: 52 | Recruiting;<br><br>Estimated primary completion: February 22, 2022 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **AG0301-COVID19, Osaka University/AnGes/Takara Bio**<br><br>DNA plasmid vaccie + adjuvant<br><br>Sponsor: AnGes, Inc<br><br>Collaborator:<br>Japan Agency for Medical Research and Development | JapicCTI-205328<br><br>https://www.clinicaltrials.jp/cti-user/trial/ShowDirect.jsp?clinicalTrialId=30761<br><br>NCT04463472<br><br>Phase 1 | Osaka City University Hospital, Japan | Phase 1<br>A Non-randomized, Open-label, Non-controlled Phase I/II Study to Assess Safety and Immunogenicity of Two Doses of Intramuscular AG0301-COVID19 (1mg/2mg) in Healthy Adults<br><br>N=30 | Incidence of Treatment-Emergent Adverse Events [Safety and Tolerability]) [ Time Frame: Week 1 through Week 9 ]<br><br>Immunogenicity [ Time Frame: Weeks 3, 5, 7, 9 ] | Acctive, not recruiting<br>Estimated primary completion date: September 26, 2020<br><br>Duration: 25.6.2020-31.7.2021 | High |
| **AG0302-COVID19, AnGes**<br><br>DNA plasmid vaccie + adjuvant<br><br>Sponsor: AnGes | NCT04527081<br><br>Phase 1/2 | Japan | Randomized, Open-label, Non-controlled Phase I/II Study to Assess Safety and Immunogenicity of Twice or Three Times Dosing of Intramuscular AG0302-COVID19 (2mg) in Healthy Adults<br>N=30 | Incidence of Treatment-Emergent Adverse Events [Safety and Tolerability] [ Time Frame: Week 1 through Week 9 ]<br><br>Immunogenicity [ Time Frame: Weeks 3, 5, 7, 9 ] | Recruiting;<br>Estimated Primary Completion:<br>November 26, 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **DNA plasmid vaccine, Cadila Healthcare Limited** | CTRI/2020/07/026352<br><br>Phase 1/2 | India | A prospective, randomized, adaptive, phase I/II clinical study to evaluate the safety and immunogenicity of Novel Corona Virus -2019-nCov vaccine candidate<br>N=1048<br><br>3 doses | Phase I: To evaluate the safety of Novel Corona Virus-2019-nCov Vaccine Candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects. (day 0 and day 84)<br><br>Phase II: To evaluate the immunogenicity of Novel Corona Virus-2019-nCov Vaccine Candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects compared to placebo. (day 0 and day 224) | Recruiting;<br>Estimated Primary Completion:<br>July 13, 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **GX-19, Genexine**<br><br>Sponsor: Genexine, Inc. | NCT04445389<br><br>Phase 1/2 | Republic of Korea | A Phase 1/2a, Multi-center, Randomized, Double-blind, Placebo-controlled Study to Investigate the Safety, Tolerability, and Immunogenicity of GX-19<br>N=210 | Incidence of solicited adverse events [ Time Frame: Through 1 year post vaccination ]<br><br>Incidence of unsolicited adverse events [ Time Frame: Through 1 year post vaccination ]<br><br>Incidence of serious adverse events [ Time Frame: Through 1 year post vaccination ] | Recruiting;<br>Estimated Primary Completion:<br>March 17, 2021 | High |

## Non-replicating viral vector

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **AZD1222, ChAdOx1 nCoV-19, Oxford and Astra-Zeneca**<br><br>Based on adenovirus vaccine vector with SARS-CoV-2 spike protein. | NCT04324606<br><br>2020-001072-15<br><br>COV001<br><br>Phase 1/2 | UK | A Phase I/II Study<br>Single-blinded, randomised, placebo controlled, multi-centre study<br>N: 510<br>Healthy volunteers aged 18-55<br>Number of study participants has been increased to 1112. | Number of virologically confirmed (PCR positive) symptomatic cases of COVID-19<br><br>Occurrence of serious adverse events (SAEs) throughout the study duration | Active, not recruiting<br><br>Estimated primary Completion:<br>October 2021 | High |
| **AZD1222, ChAdOx1 nCoV-19** | NCT04444674<br><br>PACTR202006922165132<br><br>Phase 1/2 | Multicentre study in South Africa | An Adaptive Phase I/II Randomized Placebo-controlled double-blinded Trial to Determine Safety, Immunogenicity and Efficacy of Non-replicating ChAdOx1 SARS-CoV-2 Vaccine in South African Adults Living Without HIV; and Safety and Immunogenicity in Adults Living With HIV<br><br>N=2000 | Incidence of adverse events in HIV-negative and HIV-positive adults [ Time Frame: Up to 12 months post enrollment ]<br><br>Determine if there is a reduction of severe and non-severe COVID-19 disease in HIV-negative adults who receive candidate vaccine ChAdOx1 nCoV-19 compared to placebo recipients (efficacy) [ Time Frame: Up to 12 months post enrollment ]<br><br>Assess cellular and humoral Immunogenicity of ChAdOx1 nCoV-19 in people living with HIV [ Time Frame: Up to 12 months post enrollment ] | Recruiting;<br><br>Estimated Primary Completion: October 2020 | High |
| **AZD1222, ChAdOx1 nCoV-19** | NCT04568031<br><br>Phase 1/2 | Japan | A Phase I/II Randomized, Double-blind, Placebo-controlled Multicentre Study in Participants Aged 18 Years or Older to Determine the Safety and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19<br><br>N=12 | Proportion of participants who have a post treatment sero response [ Time Frame: Day 29 or Day 57 ] | Recruiting;<br>Estimated Primary Completion: September 6, 2021 | High |
| **AZD1222, ChAdOx1 nCoV-19** | NCT04400838<br><br>2020-001228-32<br><br>Phase 2/3 | UK | Phase II/III study to determine the efficacy, safety and immunogenicity of the ChAdOx1 nCoV-19 in healthy UK volunteers.<br>A randomised, single blinded trial. | Efficacy: Number of virologically confirmed (PCR positive) symptomatic cases of COVID-19 [ Time Frame: 6 months ] | Recruiting;<br><br>Estimated primary completion: August 2021 | High |

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| | | | N= 10,260 adults and children<br>Phase 2 study: from 5 years of age<br>Phase III study: from 18 years<br><br>Comparator: Menveo or Nimenrix (meningococcal vaccines) | Safety: Occurrence of serious adverse events (SAEs) throughout the study duration. [ Time Frame: 6 months ] | | |
| **AZD1222, ChAdOx1 nCoV-19** | ISRCTN89951424<br><br>Phase 3 | Brazil | A phase III randomized controlled trial to determine safety, efficacy, and immunogenicity of the non-replicating ChAdOx1 nCoV-19 vaccine<br>Single-blind<br><br>Participants will be randomised (1:1 using block randomisation) to receive either ChAdOx1 nCoV-19 or MenACWY (licensed control vaccine). Participants will also be advised to take paracetamol for 24 hours after vaccination if there are no contraindications to doing so.<br><br>N=2000 | Virologically confirmed (PCR positive) symptomatic cases of COVID-19 over the course of 12 months.<br>All participants will be invited to follow-up visits at day 28, 90, 182 and 364 and participants will be asked to contact the study team if they develop symptoms suggestive of COVID-19 at any point during the trial. Symptomatic participants will be asked to present for a visit to test for SARS-CoV-2 PCR. | Ongoing<br>Study duration May 2020 to July 2021 | High |
| **AZD1222, ChAdOx1 nCoV-19** | NCT04516746<br><br>Phase 3 | USA | A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19<br>N=30.000 + 18 years | Efficacy: A binary response, whereby a participant is defined as a COVID-19 case if their first case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurs ≥ 15 days post second dose of study intervention. Otherwise, a participant is not defined as a COVID-19 case.(time frame 1 year)<br><br>Safety:<br>Incidence of adverse events. (Time Frame: 28 days post each dose of study Intervention)<br>Incidence of serious adverse events, medically attended adverse events, and adverse events of special interest (from Day 1 post-treatment through Day 730)<br>Incidence of local and systemic solicited adverse events. | Not yet recruiting;<br>Estimated Primary Completion: December 2, 2020 | High |

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| | | | | (Time Frame: 7 days post each dose of study intervention. ) | | |
| **AZD1222, ChAdOx1 nCoV-19** | NCT04540393<br><br>Phase 3 | Moscow, Russia | A Phase III Open-label Study in Adults to Determine the Safety and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19.<br>N=100 | Incidence of SAEs following the first vaccination and throughout the study duration (Day 180) [Safety and Tolerability]. [ Time Frame: 180 days ] | Not yet recruiting;<br>Estimated Primary Completion Date: March 5, 2021 | High |
| **AZD1222, ChAdOx1 nCoV-19** | CTRI/2020/08/027170<br><br>Phase 2/3 | India | This is a Phase 2/3, observer-blind, randomised, controlled study in healthy adults in India, for comparison of the safety of COVISHIELD with Oxford/AZ-ChAdOx1 nCoV-19 and Placebo, and immunogenicity with Oxford/AZ-ChAdOx1 nCoV-19 in prevention of SARS CoV-2 infection. A total of 1600 eligible participants of more than or equal to 18 years of age will be enrolled the study. Of these 400 participants will be part of immunogenicity cohort and will be randomly assigned in a 3:1 ratio to receive either COVISHIELD or Oxford/AZ-ChAdOx1 nCoV-19, respectively. The remaining 1200 participants from safety cohort will be randomly assigned in a 3:1 ratio to receive either COVISHIELD or Placebo, respectively.<br>2 doses (day 1 and 29) | 1. Occurrence of causally related SAEs throughout the study duration following vaccination<br>2. Ratio of GMTs of anti-S IgG antibodies | Recruiting;<br><br>Estimated completion date: June 2020 | High |

| **Vaccine, Sponsor** | **Study identifier/link to website** | **Location** | **Study design** | **Primary outcome** | **Status of trial** | **Importance** |
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| **Ad5-nCoV, CanSino**<br><br>Recombinant Novel Coronavirus Vaccine, Adenovirus Type 5 Vector<br><br>Sponsor: CanSino Biologics Inc. | ChiCTR2000030906<br>NCT04313127<br><br>Phase 1 | Hubei, China | A single-center, open and dose-escalation phase I clinical trial for recombinant novel coronavirus (2019-COV) vaccine (adenoviral vector)<br>N=108 Healthy adults treated with 3 different doses | Adverse reactions 7 days post injection | Active, not recruiting<br><br>Estimated primary completion: Dec 30 2020 | High |

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| **Ad5-nCoV**<br>Jiangsu Province Centers for Disease Control and Prevention | NCT04568811<br><br>Phase 1 | China, Hubei | Single-center, Open-label Phase I Clinical Trial of Booster Vaccination of Adenovirus Type-5 Vectored COVID-19 Vaccine in Healthy Adults Aged 18-60 Years<br>N=89 | Occurrence of adverse reactions within 14 days after booster vaccination [ Time Frame: 0-14 days post-vaccination] | Active, not recruiting;<br>Estimated Primary Completion Date: October 25, 2020 | High |
| **Ad5-nCoV**<br><br>Institute of Biotechnology, Academy of Military Medical Sciences, PLA of China<br><br>CanSino Biologics Inc. | NCT04341389<br>ChiCTR2000031781<br><br>Phase 2 | China, Hubei | A Randomized, Double-blind, Placebo-controlled Phase II Clinical Trial to Evaluate the Safety and Immunogenicity of the Recombinant Novel Coronavirus Vaccine (Adenovirus Vector) in Healthy Adults Aged Above 18 Years<br>N=500 healthy individuals randomised to<br>1×10^11vp of Ad5-nCoV<br>5×10^10vp of Ad5-nCoV<br>Placebo | Occurrence of adverse reactions [ Time Frame: 0-14 days post vaccination ]<br>Anti SARS-CoV-2 S antibody response(ELISA) [ Time Frame: 28 days post vaccination ]<br>Neutralizing antibody response to SARS-CoV-2 [ Time Frame: 28 days post vaccination ] | Active, not recruiting;<br><br>Estimated Primary Completion:<br>January 31, 2021 | High |
| **Ad5-nCoV**<br><br>Sponsor and collaborators:<br>CanSino Biologics Inc.<br><br>Beijing institute of biotechnology<br><br>Canadian Center for Vaccinology | NCT04398147<br><br>Phase 1/2 | Canada | Phase I /II adaptive clinical trial to evaluate the safety, tolerability and the Immunogenicity of Ad5-nCoV in healthy adults from 18 to <55 and 65 to <85 years of age with the randomized, observer-blind, dose-escalation design.<br><br>N=96 will be included in the dose-escalating study (phase I)<br>5E10vp and 10E10vp,<br>Of each of the 2 doses, single dose and 2 doses will be tested.<br><br>N=600 will be included in the phase 2 trial | Solicited AE in all groups [ Time Frame: 0-6 days after each vaccination ]<br><br>Unsolicited AE in all groups [ Time Frame: 0-28 days after each vaccination ]<br><br>Serious adverse events (SAE) in all groups [ Time Frame: 6 months after the final vaccination ] | Not yet recruiting;<br><br>Estimated Primary Completion: December 2021 | High |
| **Ad5-nCoV**<br>CanSino Biologics Inc.<br>Beijing Institute of Biotechnology<br>Jiangsu Province Centers for Disease Control and Prevention | NCT04566770<br><br>Phase 2 | China, Jiangsu | A Randomized, Double-blind, Placebo-Controlled Phase IIb Clinical Trial to Evaluate the Safety and Immunogenicity of Ad5-nCoV in Person 6 Years of Age and Older and Those Who Have Previously Been Vaccinated With Ad5-EBOV<br>N=481 | Safety and immunogenicity | Recruiting;<br>Estimated Primary Completion Date : August 21, 2021 | High |

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| **A**d5-nCoV<br><br>Sponsors:<br>CanSino Biologics Inc.<br>Beijing Institute of Biotechnology | NCT04526990<br><br>Phase 3 | Pakistan | A Global Multicenter, Randomized, Double-blind, Placebo -Controlled, Adaptive Designed Phase Ⅲ Clinical Trial to Evaluate the Efficacy, Safety and Immunogenicity of Ad5-nCoV in Adults 18 Years of Age and Older<br>N=40.000 | Incidence of COVID-19 cases [ Time Frame: day 28 to 12 months post vaccination ]<br><br>Incidence of SAE [ Time Frame: Within 12 months ] | Not yet recruiting;<br>Estimated Primary Completion: December 30, 2021 | High |
| **Ad5-nCoV**<br><br>NPO Petrovax<br>CanSino Biologics Inc. | NCT04540419<br><br>Phase 3 | Russia | Multicenter, Randomized, Double Blind, Placebo Controlled Parallel Group Study Evaluating Efficacy, Reactogenicity and Safety of Recombinant Vaccine Ad5-nCoV Against Novel Coronavirus Infection in Adult Volunteers<br><br>N= 500, 18-85 years randomized 2:1 to single dose vaccine or placebo | Superiority of the vaccine Ad5-nCoV to placebo by the level of seroconversion [ Time Frame: Day 28 after vaccination ]<br>Assessed as the proportion of subjects with four-fold and higher increment of anti-receptor-binding domain antibodies [receptor-binding domain, RBD] of S-protein SARS-CoV-2). | Recruiting;<br><br>Estimated Primary Completion: November 30, 2020 | High |

| **Vaccine, Sponsor** | **Study identifier/link to website** | **Location** | **Study design** | **Primary outcome** | **Status of trial** | **Importance** |
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| **Ad26.COV2-S, JnJ**<br><br>(JNJ-78436735)<br>Sponsor:<br>Janssen Vaccines & Prevention B.V., Johnson & Johnson | NCT04436276<br><br>Phase 1/2 | US and Belgium | A Randomized, Double-blind, Placebo-controlled Phase 1/2a Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26COVS1 in Adults Aged 18 to 55 Years Inclusive and Adults Aged 65 Years and Older<br><br>N=1045<br>Cohort 1a and 1b and 3: 2 dose levels, 1 or 2 doses with 56 days interval of Ad26.COV2.S or placebo<br><br>Cohort 2a:<br>High dose or matching placebo at day 1 followed by booster at 6, 12 and 24 months.<br><br>Cohort 2b: 2 low doses or matching placebo at day 1 and 57 followed by booster at 8, 14 and 26 months after completion of primary regimen | Safety parameters | Recruiting;<br>Estimated Primary Completion: September 15, 2021 | High |

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| Ad26.COV2-S, JnJ<br><br>(JNJ-78436735)<br>Sponsor:<br>Janssen Vaccines & Prevention B.V., Johnson & Johnson | NCT04509947<br><br>Phase 1 | Japan | A Randomized, Double-blind, Placebo-controlled Phase 1 Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of Ad26.COV2.S in Adults<br>N=250 randomised to low dose, high dose or placebo.<br><br>Two injections at day 1 and 57 | Safety parameters | Recruiting;<br>Estimated Primary Completion: January 8, 2021 | High |
| Ad26.COV2-S, JnJ<br><br>(JNJ-78436735)<br>Sponsor:<br>Janssen Vaccines & Prevention B.V., Johnson & Johnson | NCT04505722<br><br>Phase 3 | US, Argentina, Brazil, Chile, Columbia, Mexico, Peru, Philippines, South Africa, Ukraine | A Randomized, Double-blind, Placebo-controlled Phase 3 Study to Assess the Efficacy and Safety of Ad26.COV2.S for the Prevention of SARS-CoV-2-mediated COVID-19 in Adults Aged 18 Years and Older<br><br>N=60000 randomised to Ad26.COV2.S 1^10*11 virus particles (vp) as single dose vaccine on Day 1 or placebo. | Number of Participants with First Occurrence of Molecularly Confirmed Moderate to Severe/Critical Coronavirus Disease (COVID-19) with Seronegative Status [ Time Frame: Up to 2.1 years ]<br>Moderate defined as one sign and one symptom from a list of signs, such as respiratory rate >90 and symptoms such as shortness of breath or cough or 2 symptoms from a list of symptoms or Severe COVID-19 defined in FDA guidance. | Recruiting;<br>Estimated Primary Completion: March 10, 2023 | High |

| **Vaccine, Sponsor** | **Study identifier/link to website** | **Location** | **Study design** | **Primary outcome** | **Status of trial** | **Importance** |
|---|---|---|---|---|---|---|
| **Gam-COVID-Vac Lyo, Gamaleya**<br><br>Adenovector virus<br><br>Gamaleya Research Institute of Epidemiology and Microbiology, Health Ministry of the Russian Federation | NCT04437875<br><br>Phase 1/2 | Moscow, Russian Federation | An open, prospective, two-stage, non-randomized, first-phase study involving healthy volunteers<br><br>N=38<br><br>3 arms:<br><br>rAd26 Component,<br>1 vaccination Component 1 consists of a recombinant adenovirus vector based on the human adenovirus type<br><br>rAd5 Component,<br>1 vaccination Component 2 consists of a vector based on the human adenovirus type 5, containing the SARS-CoV-2 S protein gene.<br><br>Prime-boost: Day 1 rAd26, | The changing of antibody levels against the SARS-CoV-2 glycoprotein S at 42 days [ Time Frame: at days 0, 14, 21, 28, 42 ]<br><br>Number of Participants With Adverse Events [ Time Frame: through the whole study, an average of 180 days ] | Completed;<br><br>Actual Primary Completion Date: August 3, 2020<br><br>Actual Study Completion Date: August 10, 2020 | High |

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| | | | Day 21 rAd5 | | | |
| **Gam-COVID-Vac**<br><br>rAd26 Component, 1 vaccination (recombinant adenovirus vector)<br><br>rAd5 Component, 1 vaccination (a vector based on the human adenovirus type 5)<br><br>Gamaleya Research Institute of Epidemiology and Microbiology, Health Ministry of the Russian Federation | NCT04436471<br><br>Phase 1/2 | Moscow, Russian Federation | An open, prospective, two-stage, non-randomized, first-phase study involving healthy volunteers<br><br>N=38<br><br>3 arms:<br><br>rAd26 Component,<br>1 vaccination Component 1 consists of a recombinant adenovirus vector based on the human adenovirus type 26<br><br>rAd5 Component,<br>1 vaccination Component 2 consists of a vector based on the human adenovirus type 5, containing the SARS-CoV-2 S protein gene.<br><br>Prime-boost: Day 1 rAd26,<br>Day 21 rAd5 | Changing ofantibody levels against the SARS-CoV-2 glycoprotein S in 42 days [ Time Frame: at days 0,14, 21, 28, 42 ]<br>Number of Participants With Adverse Events [ Time Frame: through the whole study, an average of 180 days ] | Completed;<br><br>Actual Primary Completion Date: August 3, 2020<br><br>Actual Study Completion Date: August 10, 2020 | High |
| **Gam-COVID-Vac**<br><br>Sponsor: Gamaleya Research Institute of Epidemiology and Microbiology, Health Ministry of the Russian Federation | NCT04587219<br><br>Phase 2 | Russian | An Open Study of the Safety, Tolerability and Immunogenicity of the "Gam-COVID-Vac"Vaccine Against COVID-19 (Solution for Intramuscular Injection) With the Participation of Volunteers in the Age Group Over 60 Years<br>Single arm<br>N=110 | Changing of antibody levels against the SARS-CoV-2 glycoprotein S in 42 days [ Time Frame: at days 0, 21, 28, 42 ]<br><br>Number of Participants With Adverse Events [ Time Frame: through the whole study, an average of 180 days ] | Not yet recruiting;<br>Estimated Primary Completion Date : December 15, 2020 | High |
| **Gam-COVID-Vac**<br><br>Gamaleya Research Institute of Epidemiology and Microbiology, Health Ministry of the Russian Federation<br><br>Government of the city of Moscow<br><br>CRO: Crocus Medical BV | NCT04530396<br><br>Phase 3 | Russia | Randomized Double-blind Placebo-controlled Multi-center Clinical Trial in Parallel Assignment of Efficacy, Safety, and Immunogenicity of Gam-COVID-Vac Combined Vector Vaccine in SARS-CoV-2 Infection Prophylactic Treatment<br><br>N=40.000 randomised 3:1 to Gam-COVID-Vac combined vector vaccine, 0,5ml/dose+0,5 ml/dose prime-boost immunization in days 1 (component I rAd26-S) and 21(component II rAd5-S) or placebo | Percentage of trial subjects with coronavirus disease 2019 (COVID-19) developed within 6 months after the first dose [ Time Frame: through the whole study, an average of 180 days ] | Recruiting, Estimated Primary Completion: May 1, 2021 | High |

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| **Gam-COVID-Vac**<br>Gamaleya Research Institute of Epidemiology and Microbiology, Health Ministry of the Russian Federation<br><br>RDIF (Russian Direct Investment Fund)<br><br>CRO: iPharma | NCT04564716<br><br>Phase 3 | Belarus | Clinical Trial of Efficacy, Safety and Immunogenicity of Combined Vector Vaccine Gam-COVID-Vac in SARS-CoV-2 Infection Prophylactic Treatment in Republic of Belarus<br>N=100 randomised 3:1 to Gam-COVID-Vac combined vector vaccine, 0,5ml/dose+0,5 ml/dose prime-boost immunization in days 1 (component I rAd26-S) and 21(component II rAd5-S) or<br>placebo | percentage of trial subjects with coronavirus disease 2019 (COVID-19) developed within 6 months after the first dose [ Time Frame: through the whole study, an average of 180 days ] | Recruiting;<br><br>Estimated Primary Completion: March 28, 2021 | High |

| **Vaccine, Sponsor** | **Study identifier/link to website** | **Location** | **Study design** | **Primary outcome** | **Status of trial** | **Importance** |
|---|---|---|---|---|---|---|
| **Grad-CoV2, ReiThera/LEUKOCARE/ Univercells**<br><br>Replication defective Simian Adenovirus (GRAd) encoding S | 2020-002835-31<br><br>https://www.reithera.com/2020/08/03/covid-19-aifa-autorizza-la-sperimentazione-di-fase-i-del-vaccino-reithera-in-italia/<br><br>NCT04528641<br><br>Phase 1 | Italy | A phase 1 dose escalation study to evaluate the safety and immunogenicity of GRAd-CoV2. The study involves 90 healthy volunteers in two sequential cohorts (adult cohort and elderly cohort): 18-55 years and 65-85 years.<br><br>N=90<br>There are three treatment arms (with three increasing doses of vaccine), consisting of 15 participants each, for a total of 6 groups. | Safety measures | Recruiting;<br><br>Adult enrolment is expected to end in the second week of September and the first safety and immunogenicity results will be available by the second week of October.<br>The enrolment of the elderly will end in the first week of November and the first results will arrive by the second week of December. Final safety and immunogenicity data will be available within one year of study approval.<br>Estimated primary completion: July 31, 2021 | High |

| **Vaccine, Sponsor** | **Study identifier/link to website** | **Location** | **Study design** | **Primary outcome** | **Status of trial** | **Importance** |
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| **Ad5-nCoV**<br><br>Muccosal and IM administration<br><br>Sponsor: Institute of Biotechnology, Academy of Military Medical Sciences, PLA of China | NCT04552366<br><br>Phase 1 | China, Hubei | A Clinical Trial to Evaluate the Safety and Immunogenicity of a Recombinant Adenovirus 5 Vectored COVID-19 Vaccine (Ad5-nCoV) With Two Doses in Healthy Adults Aged 18 Years and Older.<br><br>The safety and immunogenicity of intramuscular vaccination and mucosal vaccination of two doses of Ad5-nCoV in different administration schedules will be evaluated<br><br>N=144 | Safety and immunogenicity | Recruiting;<br><br>Estimated Primary Completion: December 31, 2020 | High |

## Replicating viral vector

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **TMV-083, Institute Pasteur/Themis/Univ. of Pittsburg CVR/Merck Sharp & Dohme**<br><br>Measles-vector based<br><br>Sponsor: Institut Pasteur<br>Collaborators: Themis Bioscience GmbH<br>Coalition for Epidemic Preparedness Innovations (CEPI) | NCT04497298<br><br>Phase 1 | Belgium, France | A Randomized, Placebo-controlled Trial, to Evaluate the Safety and Immunogenicity of the COVID-19 Vaccine, a Measles Vector-based Vaccine Candidate Against COVID-19 in Healthy Volunteers Consisting of an Unblinded Dose Escalation and a Blinded Treatment Phase.<br><br>N=90.<br>2 doses and 2 regimens will be tested. | To assess the safety and tolerability of the COVID-19 vaccine following one or two consecutive intramuscular injections in healthy volunteers [ Time Frame: Day 390 ] | Recruiting;<br><br>Estimated primary completion: November 2020 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **V591-001, Themis/Merck Sharp & Dohme**<br><br>Measles-vector based<br><br>Sponsor: Merck Sharp & Dohme Corp. | NCT04498247<br><br>Phase 1/2 | Belgium, France | A Phase 1/Phase 2, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Trial to Evaluate the Safety, Tolerability and Immunogenicity of V591 (COVID-19 Vaccine) in Healthy Younger and Older Participants<br>N=260 | Adverse events up to 365 days post vaccination | Recruiting;<br><br>Estimated primary completion: March 16, 2022 | High |

## Inactivated virus

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **Coronavac, Sinovac**<br><br>Formalin-inactivated and alum-adjuvanted<br><br>Inactivated SARS-CoV-2 vaccine (Vero Cell)<br><br>Sponsor: Sinovac Research & Development Co., Ltd | NCT04352608<br><br>Phase1/2 | China, Jiangsu | Randomized, double-blinded, and placebo controlled phase I/II clinical trial of the SARS-CoV-2 inactivated vaccine.<br><br>Healthy adults aged 18-59 Years.<br>N (estimated) = 744 | 1.Safety indexes of adverse reactions [ Time Frame: up to 28 days after the whole schedule vaccination ]<br><br>2.Neutralizing-antibody seroconversion rates for the emergency vaccination schedule (0 and 14) [ Time Frame: The 14th day after two doses of vaccination ]<br><br>3.Neutralizing-antibody seroconversion rates for the routine vaccination schedule (day 0,28) [ Time Frame: The 28th day after two doses of vaccination ] | Active, not recruiting;<br><br>Actual Primary Completion Date: July 10, 2020 | High |
| | NCT04383574<br><br>Phase 1/2 | China, Hebei | Phase 1/2, double-blinded, placebo-controlled, randomized trial for Prevention of Covid-19 infection.<br><br>N = 422 (72 in phase 1 and 350 in phase 2), age ≥ 60, healthy, randomized to two doses of low, medium or high dosage or placebo | Safety index-incidence of adverse reactions [Time Frame: Day 0-28 after each dose vaccination] | Active, not recruiting;<br><br>Actual Primary Completion Date: August 28, 2020 | High |
| | NCT04551547<br><br>Phase 1/2 | China, Hebei | A Randomized, Double-Blinded, Placebo-Controlled, Phase Ⅰ/Ⅱ Clinical Trial.<br>2 dose regimen day 0 and 28.<br>N=552, 3-17 years old<br>Randomised to low dose (300SU/0.5ml), medium dose (600SU/0.5ml) or placebo | Safety index-incidence of adverse reactions [ Time Frame: Day 0-28 after each dose vaccination ]<br><br>Immunogenicity index-seroconversion rates of neutralizing antibody [ Time Frame: The 28th day after the second dose vaccination ] | Not yet recruiting;<br><br>Estimated Study Start Date: September 28, 2020<br><br>Estimated Primary Completion: January 2021 | High |
| **Coronavac, Sinovac**<br><br>Sponsor: Sinovac Research and Development Co., Ltd. | NCT04456595<br><br>Phase 3 | Brazil | Double-Blind, Randomized, Placebo-Controlled Phase III Clinical Trial to Evaluate Efficacy and Safety in Healthcare Professionals of the Adsorbed COVID-19 (Inactivated) Vaccine Manufactured by Sinovac<br><br>N= 8870 | Incidence of COVID-19 cases after two-doses immunization schedule [ Time Frame: Two weeks after second dose up to one year after first dose ]<br>Number of virologically-confirmed symptomatic | Recruiting;<br><br>Estimated primary completion date: September 2021 | High |

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| Collaborator. Butantan Institute | | | | COVID-19 two weeks after second dose of vaccine<br><br>Frequency of adverse events [ Time Frame: Seven days after each immunization ]<br>Frequency of adverse reaction in the seven days following each immunization per age group | | |
| **Sinovac**<br><br>Sponsor: PT Bio Farma, Collaborators: Faculty of Medicine Universitas Padjadjaran.<br>National Intitute of Health Research and Development, Ministry of Health Republic of Indonesia.<br>Sinovac Life Sciences Co., Ltd. | NCT04508075<br><br>https://www.ina-registry.org/index.php?act=registry_trial_detail&code_trial=162020090807 21WXFM0YX<br>669/UN6.KEP/EC/2020<br><br>Phase 3 | Indonesia | A Phase III, Observer-blind, Randomized, Placebo-controlled Study of the Efficacy, Safety and Immunogenicity of SARS-CoV-2 Inactivated Vaccine in Healthy Adults Aged 18-59 Years in Indonesia.<br><br>N=1620 randomised to Sinovac vaccine or placeno | Incidence of laboratory-confirmed COVID-19 after the second dose [ Time Frame: 14 days to 6 months after the second dose ]<br>Percentage of laboratory-confirmed COVID-19 cases | Recruiting;<br>Estimated Primary Completion; January 2021 | High |
| Sinovac,<br><br>Sponsor: Health Institutes of Turkey | NCT04582344<br><br>Phase 3 | Turkey | Randomized, Double-Blind, Placebo-Controlled Phase III Clinical Trial For Evaluation of Efficacy and Safety of SARS-CoV-2 Vaccine (Vero Cell), Inactivated<br><br>N=13,000 randomised to vaccine or placebo, to doses with 14 days interval | Protection Indexes of Two Vaccine Doses For Symptomatic COVID-19 [ Time Frame: 2 weeks after the second dose of vaccination ] | Recruiting;<br>Estimated Primary Completion Date : February 15, 2021 | High |

| **Vaccine, Sponsor** | **Study identifier/link to website** | **Location** | **Study design** | **Primary outcome** | **Status of trial** | **Importance** |
|---|---|---|---|---|---|---|
| **Wuhan Institute of Biological Products, Sinopharm**<br><br>Inactivated vaccine (Vero cells)<br>Henan Provincial Center for Disease Control and Prevention<br>Funding: | ChiCTR2000031809<br><br>Phase 1/2 | China, He'nan , Jiaozuo | Randomized, double-blind, placebo parallel-controlled phase I/II clinical trial for inactivated Novel Coronavirus Pneumonia vaccine (Vero cells)<br><br>Healthy volunteers, from 6 years of age<br>Multiple doses | Incidence of adverse reactions/events | From 2020-04-11 To 2021-11-10 | High |

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| Ministry of Science and Technology, China | | | | | | |
| **Wuhan vaccine**<br><br>Sponsor: China National Biotec Group Co.Ltd | ChiCTR2000039000<br><br>Phase 3 | Marocco | Randomized, double-blinded, placebo parallel-controlled phase III clinical trial to evaluate the Immunogenicity and safety of the inactivated SARS-CoV-2 Vaccine (Vero cell) in healthy population aged 18 years and above<br><br>N=600 | To evaluate the 4-fold increase rate, GMT and GMI of anti-SARS-CoV-2 neutralizing antibody 28 days after full course of immunization | From2020-09-02To 2020-12-31 | |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **Beijing Institute of Biological Products, Sinopharm**<br><br>Inactivated vaccine (Vero cells)<br>Sponsor: Henan Provincial Center for Disease Control and Prevention<br>Funding:<br>Ministry of Science and Technology, China<br>and Sinopharm | ChiCTR2000032459<br><br>Phase 1/2 | China, He'nan, Shangqiu | A phase 1/2 randomized, double-blind, placebo parallel-controlled clinical trial to evaluate the safety and immunogenicity of inactivated novel coronavirus (2019-CoV) vaccine (Vero cells)<br><br>N = 2128???<br>Healthy volunteers from 3 years of age<br>Multiple doses | Incidence of adverse reactions/events | From 2020-04-28 To 2021-11-28 | High |
| **Beijing Institue of Biological Products,**<br>China National Biotec Group Company Limited<br>The Huesped Foundation<br><br>Sponsor: Laboratorio Elea Phoenix S.A. | NCT04560881<br><br>Phase 3 | Argentina | Randomized, Double Blind, Placebo Parallel-controlled Phase III Clinical Trial to Evaluate the Efficacy, Immunogenicity and Safety of the Inactivated SARS-CoV-2 Vaccine (Vero Cell) in Argentine Healthy Population Aged Between 18 and 85 Years<br><br>2 doses, day 0 and 21<br><br>N=3000 randomised to BIBP vaccine or placebo | Incidence of COVID-19 cases after two-doses of vaccination<br>[ Time Frame: 14 days after the full course of vaccination ] | Recruiting;<br><br>Estimated Primary completion: December 1 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **Wuhan AND Beijing vaccine**<br><br>Primary sponsor:<br>China National Biotec Group Co.Ltd<br><br>Collaborators:<br>G42 Healthcare company;<br>Abu Dhabi Health Services Company;<br>Wuhan Institute of Biological Products Co., Ltd;<br>Beijing Institute of Biological Products Co., Ltd | ChiCTR2000034780<br><br>NCT04510207<br><br>Phase 3 | Abu Dhabi, Peru, Morocco and Argentina, Jordan, Bahrain | Phase III trial:<br>Randomized, Double Blind, Parallel Placebo Controlled, Phase III Clinical Trial to Evaluate the Safety and Protective Efficacy of Inactivated SARS-CoV-2 Vaccine in Healthy Population Aged 18 Years and above<br><br>45000 subjects randomized 1:1:1 to two different treatment groups or placebo | The incidence of COVID-19 cases after two-doses of vaccination [ Time Frame: From14 days after the second dose to 6 month after the second dose ] | Rercruiting;<br><br>Estimated Primary Completion: March 16, 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **Chinese Academy of Medical Sciences**<br><br>Inactivated SARS-CoV-2 vaccine;<br>Sponsors and Collaborators:<br>Chinese Academy of Medical Sciences,<br>West China Second University Hospital,<br>Yunnan Center for Disease Control and Prevention | ChiCTR2000032459<br><br>NCT04412538<br><br>Phase 1/2 | China, Sichuan | Randomized, double-blinded, and placebo-controlled phase Ia/IIa clinical trial<br><br>N =942 healthy volunteers from 18-59 years of age:<br>N=192 in the phase I trial, and N=750 in the phase II trial.<br><br>Multiple doses, 2 different schedules | Incidence of adverse reactions/events<br><br>Serum conversion rate of neutralizing antibodies and IgG antibodies in the phase II trial at day 14 and 28 | Recruiting;<br>Estimated primary completion date: September 2020 | High |
| Chinese Academy of Medical Sciences<br><br>Sponsors and Collaborators<br>Chinese Academy of Medical Sciences<br>West China Second University Hospital | NCT04470609<br><br>Phase 1/2 | China, Sichuan | A Randomized, Double-blind, Placebo-controlled, Phase Ib/IIb Trial of an Inactivated SARS-CoV-2 Vaccine in Healthy People Aged ⩾60 Years<br><br>N=471 ranodmised to 1 of 3 doses or placebo.<br>1 dose at day 0 and 1 dose at day 28 | Adverse reactions/events rate [ Time Frame: 7 days and 28 days after vaccination ]<br><br>Seroconversion rate of Neutralizing antibodies and IgG antibodies against SARS-CoV-2 Phase IIb [ Time Frame: 28 days after vaccination ] | Enrolling by invitation<br>Estimated Primary Completion Date: November 2020 | High |

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| Yunnan Center for Disease Control and Prevention | | | | | | |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **QazCovid-in® - COVID-19 inactivated vaccine**<br>Sponsor: Research Institute for Biological Safety Problems | NCT04530357<br><br>Phase 1/2 | Kazakhstan | Randomized, Blind, Placebo-controlled Phase- i Study and Randomized, Open Phase Phase-ii Study of QAZCOVID-IN®- COVID-19 Inactivated Vaccine in Healthy Adult Volunteers From 18 Years Old and Elder<br>N=244 | Safety and immunogenicity | Enrolling by invitation;<br><br>Estimated Primary Completion: December 1, 2020 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **BBV152, Bharat Biotech**<br><br>Whole-Virion Inactivated SARS-CoV-2 Vaccine | CTRI/2020/07/026300<br><br>NCT04471519<br><br>Phase 1/2 | India | Phase 1, followed by Phase 2 Randomized, Double-blind, Multicenter Study to Evaluate the Safety, Reactogenicity, Tolerability and Immunogenicity of the Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) in Healthy Volunteers.<br>Whole-Virion Inactivated SARS-CoV-2 vaccine (BBV152) with three formulations, BBV152A, BBV152B and BBV152C. Dose: 0.5ml, Route of administration: Intramuscular injection, Frequency: Two doses at Day 0 and Day 14<br><br>N=1125 | Phase 1:<br>1. The occurrence of immediate adverse events within two hours of vaccination<br>2. The occurrence of adverse events within 7 days of vaccination.3. The occurrence of any adverse events throughout the study duration<br>4. The occurrence of serious adverse events (SAEs)<br><br>Phase 2:<br>Primary<br>1. To evaluate the immunogenicity in terms of GMT and four-fold seroconversion rate amongst the two selected BBV152 vaccine formulations | Recruiting;<br><br>Estimated Primary Completion Date: June 2021 | High |
| BBV152, Bharat Biotech | CTRI/2020/09/027674 | India | An Adaptive, Seamless Phase 1, Followed by a Phase 2, Randomized, Multicenter Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of the Whole Virion Inactivated SARS-CoV- 2 Virus Vaccine, BBV152D Administered Intradermally in Healthy Volunteers. | Phase 1<br>1. The occurrence of immediate adverse events within two hours of vaccination.<br>2. The occurrence of adverse events within seven days . | Recruiting;<br><br>Estimated Primary Completion Date: June 2021 | High |

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| | | | N=124 | 3. The occurrence of any adverse events throughout the study duration<br>4. The occurrence of serious adverse events (SAEs).<br><br>Phase 2<br>1. To evaluate the immunogenicity in terms of four-fold seroconversion rate of SARSCoV-<br>2 virus neutralizing antibodies across the two dosage strengths of BBV152D. | | |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **Inactivated vaccine, Jiangsu**<br><br>Jiangsu Provincial Center for Disease Control and Prevention(Public Health Research Institute of Jiangsu Province)<br><br>Beijing Minhai Biotechnology | ChiCTR2000038804<br><br>Phase 1 | Jiangsu, China | Evaluation of the safety and immunogenicity of inactivated SARS-CoV-2 Vaccine(Vero Cells) in healthy population aged 18 years and above: a randomized, double-blind, placebo parallel-controlled phase I clinical trial<br>N=180 | Incidence of adverse reactions/events | From2020-10-07To 2022-04-06 | High |

## Protein subunit

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **NVX-CoV2373, Novavax**<br><br>SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS)<br><br>Sponsor:<br>Novavax<br><br>CEPI funding | NCT04368988<br><br>Phase 1/2 | Australia (multiple sites) and US | A 2-Part, phase 1/2, randomized, observer-blinded study to evaluate the safety and immunogenicity of a SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with or without MATRIX-M™ Adjuvant in healthy subjects.<br><br>N= 1419 healthy subjects aged 18 to 84 years | Safety and immunogenicity measures | Active, not recruiting;<br><br>Estimated Primary Completion Date: December 31, 2020 | High |
| NVX-CoV2373<br><br>Sponsor: Novavax | NCT04533399<br><br>Phase 2 | South Africa | A Phase 2A/B, Randomized, Observer-blinded, Placebo-controlled Study to Evaluate the Efficacy, Immunogenicity, and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) With Matrix-M1™ Adjuvant in South African Adult Subjects Living Without HIV; and Safety and Immunogenicity in Adults Living With HIV.<br>N= 2904, 18 to 64 years randomised to vaccine or placebo.<br>2 doses | Diagnosis of COVID-19, immunogenicity and safety measures | Recruiting;<br>Estimated Primary Completion: November 2021 | High |
| NVX-CoV2373<br><br>Sponsor: Novavax | 2020-004123-16<br><br>Phase 3 | UK | A Phase 3, Randomised, Observer-Blinded, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of a SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1<br><br>N=9,000 | • FIRST PRIMARY ENDPOINT: First occurrence of virologically confirmed (by PCR to SARS-CoV-2), symptomatic COVID-19 with onset at least 7 days after second study vaccination (e.g., Day 28) in serologically negative (to SARS-CoV-2) adult participants at baseline until the endpoint-driven efficacy analysis is triggered by the occurrence of a prespecified number of blinded endpoints.<br><br>• SECOND PRIMARY ENDPOINT: First occurrence of virologically confirmed (by PCR to SARS-CoV-2), symptomatic moderate or severe COVID-19 | Ongoing;<br><br>Estimated primary completion: October 2021 | High |

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| | | | | with onset at least 7 days after second study vaccination (e.g., Day 28) in serologically negative (to SARS-CoV-2) adult participants at baseline until the endpoint-driven efficacy analysis is triggered by the occurrence of a prespecified number of blinded endpoints. | | |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **Adjuvanted recombinant protein (RBDDimer), Anhui Zhifei Longcom Biologic Pharmacy Co., Ltd.**<br><br>Collaborators: The Second Affiliated Hospital of Chongqing Medical University<br>Beijing Chao Yang Hospital | NCT04445194<br><br>Phase 1 | China, Chongqing | A Multi-center, Double-blind, Randomized, Placebo Parallel Controlled, Safety and Tolerability Phase I Clinical Trial of Recombinant Novel Coronavirus Vaccine (CHO Cells) in Healthy People Between 18 and 59 Years of Age.<br>N=50 | The number of adverse events after intramuscular injection [ Time Frame: Up to one year after the last vaccination ] | Recruiting;<br><br>Estimated primary completion: July 21, 2021 | High |
| Sponsor: Anhui Zhifeilongkoma Biopharmaceutical Co., Ltd.<br>Hunan Provincial Center for Disease Control and Prevention | ChiCTR2000035691,<br><br>NCT04550351<br><br>Phase 1/2 | Hu'nan, China | A randomized, double-blind, placebo-controlled phase I clinical trial for evaluation of the safety and tolerability of recombinant novel coronavirus vaccines (CHO cells) in healthy people aged 60 years and above<br>N=50 | SARS-CoV-2 neutralizing antibody,<br>S protein binding antibody (IgG),<br>RBD protein binding antibody (IgG) detection. | Recruiting;<br><br>Estimated Primary Completion; October 31, 2021 | High |
| Sponsor:<br>Anhui Zhifei Longcom Biologic Pharmacy Co., Ltd. | NCT04466085<br><br>Phase 2 | China, Changsha | A Randomized, Blinded, Placebo-controlled Trial to Evaluate the Immunogenicity and Safety of a Recombinant New Coronavirus Vaccine (CHO Cell) With Different Doses and Different Immunization Procedures in Healthy People Aged 18 to 59 Years<br>N=900 randomised to<br>Low dose, high dose or placebo injected as 2 doses or 3 doses | Neutralizing antibody positive conversion rate [ Time Frame: 30 days after inoculation ] | Recruiting;<br>Estimated Primary Completion Date; September 15, 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **KBP-COVID-19, Kentucky Bioprocessing, Inc**<br><br>RBD-based vaccine | NCT04473690<br><br>Phase 1/2 | Not stated yet | A Phase I/II, First-in-human, Observer-blinded, Randomized, Placebo-controlled, Parallel Group Study to Evaluate the Safety and Immunogenicity of KBP-COVID-19 Vaccine in Healthy Seronegative Adults Aged 18-49 and 50-70. Two doses will be tested.<br><br>N=180 | Solicited Administration site reactions [ Time Frame: 7 days after vaccination ]<br>Occurrence of Adverse Events<br><br>Solicited systemic events [ Time Frame: 7 days after vaccination] | Not yet recruiting;<br><br>Estimated primary completion: March 25, 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **S protein**<br><br>Protein subjunit<br><br>Sponsor:<br>Sanofi Pasteur, a Sanofi Company<br>GlaxoSmithKline | NCT04537208<br><br>Phase 1/2 | US | Immunogenicity and Safety of SARS-CoV-2 Recombinant Protein Vaccine Formulations (With or Without Adjuvant) in Healthy Adults 18 Years of Age and Older<br><br>N=440 | Safety and immunogenicity | Recruiting;<br>Estimated Primary Completion: October 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **Native like Trimeric subunit Spike Protein vaccine, Clover/GSK/Dynavax**<br><br>SCB-2019 with and without adjuvant (AS03 or CpG 1018 plus Alum adjuvant)<br><br>Sponsor: Clover Biopharmaceuticals Inc./GSK/Dynavax | NCT04405908<br><br>Phase 1 | Australia | This is a randomized, double blind, placebo controlled, first-in-human study to assess safety, reactogenicity, and immunogenicity of SCB-2019 at multiple dose levels, administered as 2 injections IM in healthy subjects. Each study vaccine dose level will be evaluated with and without adjuvant.<br><br>N=150 healthy volunteers stratified by age, randomised to 1 of 3 doses (3, 9 or 30 microgram with or without adjuvant) | Incidence of solicited adverse events (AEs) after vaccination [ Time Frame: 7 days after the first or second vaccination. ]<br>Incidence of unsolicited AEs after vaccination [ Time Frame: Day 1 to Day 50 ]<br>Immunogenicity(Anti-SCB-2019 Antibody Titers) [ Time Frame: Day 1 to Day 184 ]<br>Geometric mean titer (GMT).<br>Geometric mean ratio (GMR).<br>Seroconversion rate (SCR).<br><br>Incidence of serious AEs (SAEs) and adverse events of special interest (AESIs) [ Time Frame: Day 1 to Day 184 ] | Recruiting;<br><br>Estimated primary completion: October 20, 2020 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **COVAX19, Recombinant spike protein with Advax™ adjuvant, Vaxine Pty Ltd/Medytox** | NCT04453852<br><br>Phase 1 | Australia, South Australia | A Randomised, Controlled, Phase 1 Study to Evaluate the Safety and Immunogenicity of a Candidate Adjuvanted Recombinant Protein SARS-COV-2 Vaccine in Healthy Adult Subjects.<br>N=40 | Incidence of Adverse Events [ Time Frame: 1 weeks post immunisation ]<br><br>COVID19 neutralizing antibody titers [ Time Frame: 2 weeks post second immunisation ]<br><br>COVID19 T cell immunogenicity [ Time Frame: 3 weeks post second immunisation ] | Recruiting;<br><br>Estimated primary completion: July 1, 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **Molecular clamp stabilized Spike protein with MF59 adjuvant, University of Queensland/CLS/Seqirus**<br><br>(MF59 adjuvanted SARS-CoV-2 Sclamp vaccine) | ACTRN12620000674932p<br><br>https://www.anzctr.org.au/<br><br>NCT04495933<br><br>Phase 1 | Australia | A Phase 1 Randomised, Double-Blind, Placebo-Controlled, Dosage-Escalation, Single Centre Study To Evaluate The Safety And Immunogenicity Of An Adjuvanted SARS-CoV-2 Sclamp Protein Subunit Vaccine (COVID-19 vaccine) In Healthy Adults Aged 18 To 55 Years Old<br>N=120 | Safety and tolerability<br><br>Total serum antibody immune responses<br><br>Neutralizing antibody (NAb) immune responses | Recruiting;<br><br>Estimated primary completion: July 1, 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **MVC-COV1901, Medigen Vaccine Biologics Corp.** | NCT04487210<br><br>Phase 1 | Taiwan | A Phase I, Prospective, Open-Labeled Study to Evaluate the Safety and Immunogenicity of MVC-COV1901<br><br>N=45. 3 doses will be tested | Safety of MVC-COV1901 [ Time Frame: Day 1 to 28 days after second vaccination ] | Not yet recruiting;<br><br>Estimated primary completion: December 31, 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **Protein subunit, Instituto Finlay de Vacunas, Cuba** | https://rpcec.sld.cu/ensayos/RPCEC00000332-Sp<br><br>Phase 1 | Cuba | Phase I / II, randomized, controlled, adaptive, double-blind and multicenter study to evaluate the safety, reactogenicity and immunogenicity of the prophylactic FINLAY-FR-1 anti-SARS-CoV-2 Vaccine Candidate in a two-dose schedule. | Serious Adverse Events-SAE. Measurement time: daily for 28 days after each dose.<br>Titer of specific anti-RBD IgG antibodies. Measurement time: Baseline and at 14, 28 and 56 days | Estimated study completion: January 11, 2021 | High |

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| | | | N=676 | | | |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
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| **EpiVacCorona, Federal Budgetary Research Institution State Research Center of Virology and Biotechnology "Vector"** | NCT04527575<br><br>Phase 1 | Russia | Simple, Blind, Placebo-controlled, Randomized Study of the Safety, Reactogenicity and Immunogenicity of Vaccine Based on Peptide Antigens for the Prevention of COVID-19 (EpiVacCorona), in Volunteers Aged 18-60 Years (I-II Phase)<br>N=100 | The proportion of vaccinated volunteers with no laboratory confirmed symptoms caused by SARS-CoV-2 within 9 months post vaccination [ Time Frame: throughout the study, an average of 270 days ] | Active, not recruiting;<br>Estimated Primary Completion: September 1, 2020 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **AdimrSC-2f, Adimmune**<br><br>Protein subunit | NCT04522089<br><br>Phase 1 | Taiwan | A Randomized, Single Center, Open-label, Dose-finding, Phase I Study to Evaluate the Safety and Immunogenicity of Pandemic Virus Vaccine, AdimrSC-2f (SARS-CoV-2), in Healthy Volunteers<br>N=70. 3 doses will be tested | The solicited adverse events (SoAEs) [ Time Frame: The 7 days following each vaccination ],<br>Incidence of abnormal laboratory tests results [ Time Frame: Day 7 after vaccination ] | Recruiting;<br><br>Estimated primary completion: November 20, 2020 | High |

## Virus Like Particles

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **RBD-HBsAg VLP**<br><br>Sponsor: Serum Institute of India Pvt Ltd | ACTRN12620000817943<br><br>Phase 1/2 | Australia | A randomized, observer-blind, placebo-controlled, Phase I/II study to evaluate the safety, reactogenicity and immunogenicity of Receptor Binding Domain (RBD) SARS-CoV-2 (COVID-19) Hepatitis B surface antigen (HBsAg) virus like particle (VLP) Vaccine in Healthy Adults<br><br>2 doses on day 0 and 28.<br>N= 280, 18-79 years old | Safety and reactogenicity<br>Immunogenicity | Recruiting;<br>Estimated primary completion: March 2021 | High |

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **Plant derived VLP, Medicago Inc./Université Laval** | NCT04450004<br><br>Phase 1 | Canada | A Randomized, Partially-Blinded, Dose-Ranging Phase 1 Study to Assess the Safety, Tolerability, and Immunogenicity of a Recombinant Coronavirus-Like Particle COVID 19 Vaccine in Adults 18-55 Years of Age<br>N=180 | Safety measures + Neutralizing antibody [ Time Frame: 21 days ]<br>Specific Th1 cell-mediated immunity (CMI) response [ Time Frame: 21 days ]<br>Specific Th2 cell-mediated immunity (CMI) response [ Time Frame: 21 days ] | Active, not recruiting;<br><br>Estimated primary completion: September 12, 2020 | High |

## Other vaccine studies, not yet recruiting

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| DNA vaccine: bacTRL-Spike<br><br>Plasmids containing synthetic DNA encoding spike protein from SARS-CoV-2<br>Sponsor: Symvivo Corporation (A Vancouver-based biotech company)<br><br>Sponsor: Symvivo Corporation | NCT04334980 | Canada, British Columbia<br>Canada, Nova Scotia | A Phase 1, Randomized, Observer-Blind, Placebo-Controlled Trial to Evaluate the Safety, Tolerability and Immunogenicity of the bacTRL-Spike Oral Candidate Vaccine for the Prevention of COVID-19 in Healthy Adults<br>N=84<br>3 different doses will be tested | Frequency of Adverse Events<br><br>Each participant will remain in the trial for 12-13 month | Not yet recruiting;<br>Estimated Primary Completion Date: August 31, 2021 | High |
| Non-Replicating Viral Vector:<br><br>Intranasal vaccine<br><br>Single dose AdCOVID | Early news:<br><br>Collaboration between University of Alabama at Birmingham and Altimune Inc.<br><br>https://www.drugtargetreview.com/news/59182/biotech-and-academia-collaborate-on-intranasal-covid-19-vaccine-development/ | USA | Phase I estimated to start Q3 2020 | TBD | Not recruiting;<br><br>Estimated study completion: Unknown | High |
| Dendritic Cell Vaccine<br><br>Sponsor: Aivita Biomedical, Inc. | NCT04386252 | US | A phase 1/2, randomized, double-blinded trial of a vaccine consisting of autologous dendritic cells loaded with antigens from SARS-CoV-2, with or without GM-CSF, to prevent COVID-19. Different doses<br><br>N = 160 frontline healthcare providers and first responders. | Confirm safety [ Time Frame: 6 months ] | Not yet recruiting<br><br>Estimated Primary Completion Date: October 2020 | High |
| Drug: MicroRNA2911<br><br>Sponsor: Nanjing University | ChiCTR2000031432 | China, Jiangsu | Phase 1, single center, randomized, open, dose-increasing, double-blind clinical study to evaluate the safety | Safety and tolerance | Not yet recruiting<br><br>From 2020-04-01 To 2020-08-31 | Medium |

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| | | | and tolerance of microRNA2911 plasmid in healthy people.<br><br>N = 15 healthy adults enrolled in 1-5 dose group to receive 3 times of intravenous infusion for 10 minutes of MicroRNA2911 once a day or every other day. | | | |

## Other vaccines

| Vaccine, Sponsor | Study identifier/link to website | Location | Study design | Primary outcome | Status of trial | Importance |
|---|---|---|---|---|---|---|
| **BCG vaccine**<br>Licensed for tuberculosis | NCT04327206<br><br>The BRACE trial | Murdoch Children's Research Institute in Australia | Randomised, multi-center clinical trial to test the use of BCG vaccine against COVID-19 patients<br><br>Will include 4.170 healthcare workers across AU, incl Melbourne Campus' Royal Children's Hospital | TBD<br><br>BCG will be assessed for its ability to mitigate the prevalence and severity of COVID-19 symptoms. | Recruiting;<br><br>Estimated primary completion: June 30, 2021 | High |
| BCG vaccine<br>University Medical Center, Netherlands | EudraCT: 2020-000919-69<br><br>NCT04328441 | Netherlands | Randomised placebo controlled multi-center clinical trial to test the use of BCG vaccine as protection against COVID-19<br><br>Will include 1.000 healthcare workers across 8 Dutch hospitals<br><br>BCG often cause an injection site reaction which will unblind the person receiving BCG, but the researchers will remain blinded. | Study outcome: "unplanned absenteeism" as it will not be feasible to visit the sick professionals at home during the coronavirus pandemic<br><br>BCG will be assessed for its ability to mitigate the prevalence and severity of COVID-19 symptoms. | Active, not recruiting;<br><br>Estimated Primary Completion: March 31, 2021 | High |
| BCG vaccine<br><br>BCG vaccine is the Copenhagen (Danish strain)<br><br>Sponsor:<br>Ain Shams University | NCT04350931 | Egypt | Single blind, randomised, placebo controlled trial.<br><br>N=900 healthcare workers will be randomly assigned to receive intradermal injection of either BCG vaccine or normal saline. | Incidence of confirmed COVID-19 [ Time Frame: 9 months ]<br>Estimate the incidence of confirmed COVID-19 among the healthcare workers in isolation hospitals<br><br>Effectiveness of BCG vaccine [ Time Frame: 9 months ]<br>Evaluate the effectiveness of BCG vaccine in protecting the healthcare workers in isolation | Not yet recruiting;<br>Estimated Primary Completion: October 1, 2020 | High |

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| | | | | hospitals against the risk of COVID-19 infection by detecting any positive cases among vaccinated healthscare workers | | |
| BCG Vaccine<br><br>Sponsor:<br>Andrew Dinardo | NCT04348370 | United States: Massachusetts and Texas | Phase 4, randomized, double-blinded<br><br>N=700 health care workers randomized 1:1 to BCG vaccine or placebo. | Incidence (measured by confirmed positive test) of SARS-CoV2 infection following BCG vaccination compared to placebo [ Time Frame: Measured daily for up to 6 months ] | Recruiting<br><br>Estimated Primary Completion Date: May 2021 | High |
| BCG vaccine<br><br>Sponsor:<br>Universidad de Antioquia | NCT04362124 | Columbia (multicenter) | Phase 3, double-blind, randomized, clinical trial to evaluate the BCG vaccination in healthcare workers to reduce the severity of SARS-COV-2 infection.<br><br>N=1000 covid-19 negative health care workers randomized 1:1 to BCG vaccine or placebo. | Primary outcome [ Time Frame: From date of randomization to 360 day of the study ] | Not yet recruiting<br><br>Estimated Primary Completion Date: June 2021 | High |
| BCG vaccine<br>of patients already positive for SARS-CoV-2 (non-specific effects)<br><br>Sponsor:<br>University of Campinas, Brazil | NCT04369794<br><br>(BATTLE) | Brazil | Phase 4, prospective, randomized, double-blind, multicentre study to evaluate to the impact of previous (priming effect, from the titer of anti-BCG interferon-gamma) or current BCG exposure (boost with intradermal vaccine) on 1) clinical evolution of COVID-19; 2) elimination of SARS-CoV-2 at different times and disease phenotypes; and 3) seroconversion rate and titration (anti-SARS-CoV-2 IgA, IgM, and IgG).<br><br>N=1000 randomized to BCG vaccine or placebo. | 1. Clinical evolution of COVID-19 [ Time Frame: 45 days of symptoms onset or diagnosis ]<br><br>2. SARS-CoV-2 elimination [ Time Frame: 7 days of symptoms onset or diagnosis ]<br><br>3. Seroconversion rate and titration [ Time Frame: 7 days of symptoms onset or diagnosis | Recruiting<br><br>Estimated Study Completion Date: May 2022 | High |
| BCG vaccine<br><br>Sponsor:<br>Bandim Health Project<br><br>Collaborator:<br>University of Southern Denmark | NCT04373291<br><br>2020-001888-90<br><br>BCG-DENMARK-COVID | Denmark | Using BCG vaccine to enhance nonspecific protection of health care workers during the COVID-19 pandemic. A randomised controlled multi-center trial.<br>Phase 3, multi-center, randomized, double-blinded placebo-controlled trial using BCG Vaccine to enhance | Number of days of unplanned absenteeism for any reason [ Time Frame: 6 months ] | Not yet recruiting<br><br>Estimated Study Completion Date: January 2021 | High |

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| | | | non-specific protection of health care workers during the COVID-19 pandemic.<br><br>N=1500 hospital personal ≥18 years caring for covid-19 patients randomized 1:1 to BCG vaccine (0,1 mL dose of BCG-Denmark, AJ Vaccines) or placebo (0.1 ml dose sterile 0.9 % NaCl). | | | |
| Bacille Calmette-Guérin (BCG)<br><br>Sponsor: TASK Applied Science | NCT04379336 | South Africa | A phase 3, randomized, double-blinded, placebo-controlled study to reduce morbidity and mortality in health care workers exposed to SARS-CoV-2 by enhancing non-specific immune responses through bacillus calmette-guérin vaccination<br><br>N = 500 healthcare workers | Incidence of HCWs hospitalized due to COVID-19 per arm [ Time Frame: 52 weeks ] | Recruiting<br><br>Estimated Primary Completion Date: April 28, 2021 | High |
| BCG vaccinaton<br><br>Sponsor: Assistance Publique - Hôpitaux de Paris | NCT04384549 | France | Phase 3, single-blinded, placebo-controlled, randomized trial on the Efficacy of Vaccination With Bacillus Calmette and Guérin (BCG) in the Prevention of COVID-19 Via the Strengthening of Innate Immunity in Health Care Workers<br><br>N = 1120 healthcare workers in direct contact with Covid-19 patients | Incidence of documented COVID-19 among health care workers exposed to SARS CoV2 and vaccinated with BCG compared to placebo. [Time Frame: during the study period of 6 months] | Recruiting<br><br>Estimated Primary Completion Date: February 11, 2021 | High |
| VPM1002<br><br>(Mycobacterium bovis rBCGΔureC::hly, live 2-8 × 105 CFU) | NCT04439045 | Canada | A Randomized, Double-blind, Placebo-controlled Phase 3 Study<br>N=3626 | | Recruiting<br>Estimated Primary Completion: April 1, 2021 | High |
| VPM1002 (a further development of the BCG-vaccine)<br><br>Sponsor:<br>Vakzine Projekt Management GmbH | NCT04387409<br><br>VPM1002-DE-3.06CoV | Germany | Phase 3, double-blind, randomized, placebo-controlled multicentre trial to assess the efficacy and safety of VPM1002 in reducing healthcare professionals' absenteeism in the SARS-CoV-2 pandemic by modulating the immune system.<br><br>N=1200 health care professionals with high expected exposure to SARSCoV-2 infected patients randomized 1:1 to a single dose (0.1 ml) of either VPM1002 or placebo. | Number of days absent from work due to respiratory disease (with or without documented SARS-CoV-2 infection) [ Time Frame: From day 0 to day 240 ] | Recruiting<br><br>Estimated Primary Completion Date: June 30, 2021 | High |

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| BCG vaccination | NCT04417335 | Netherlands | Single blinded, placebo-controlled adaptive multi-centre randomized controlled trial<br>N=2014 randomised to BCG vaccination or placebo | SARS-CoV-2 related hospital admission [ Time Frame: Maximum of 1 year ] | Active, not recruiting;<br>Estimated primary completion. May 2021 | Medium |
| BCG vaccination | NCT04414267 | Greece | A Randomized double blinded Clinical Trial for Enhanced Trained Immune Responses Through Bacillus Calmette-Guérin Vaccination to Prevent Infections by COVID-19: The ACTIVATE II Trial<br><br>N=900 randomised to BCG or placebo | Positive for the respiratory questionnaire consisted of questions concerning the appearance of symptoms possibly, probably and/or definitively related to COVID-19 on visit 3. [ Time Frame: Visit 3 (90 +/- 5 days) ] | Recruiting;<br>Estimated primary completion: May 25, 2021 | Medium |

| **Vaccine, Sponsor** | **Study identifier/link to website** | **Location** | **Study design** | **Primary outcome** | **Status of trial** | **Importance** |
|---|---|---|---|---|---|---|
| **Measles-Mumps-Rubella Vaccine**<br><br>Sponsor: Kasr El Aini Hospital | NCT04357028 | Egypt | Phase 3, randomized, single-blinded, placebo-controlled clinical trial to determine the benefit of measles vaccine in health care professional.<br><br>N = 200 | COVID-19 disease incidence [ Time Frame: Time Frame: Measured over the 6 months following randomization ] | Recruiting<br>Estimated primary Completion Date: October 1, 2020 | Medium |
| **Inactivated mycobacterium vaccine**<br>Sponsor: Guangxi medical university | ChiCTR2000030016<br><br>http://www.chictr.org.cn/showproj.aspx?proj=49799 | Guangxi Zhuang, China | N=60 with<br>Covid-19 patients randomized to mycobacterium vaccine or saline | viral negative-transforming time;30-day cause-specific mortality;30-day cause-adverse events;30-day all-cause mortality;co-infections;Time from severe and critical patients to clinical improvement; | Recruiting;<br><br>Dec 12, 2022 | Medium |

Link to WHO's list of vaccines in preclinical and clinical phases, updated August 25, 2020:

https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines