

Risk of venous thromboembolism in patients with COVID-19:

A nationwide, population-based matched cohort study

Synopsis

Venous thromboembolism (VTE) is a feared complication in hospitalised patients. Corona virus disease 2019 (COVID-19) has a remarkable pro-coagulant biochemical profile, which has spurred concern for risk of VTE in these patients. This may be exacerbated by immobilisation and respiratory failure. Still, only a few retrospective observational cohort studies have specifically addressed this potential complication, and the reported risks of clinically symptomatic VTE vary considerably. Moreover, the studies to date are restricted to a single or a few centres and some have serious methodological concerns as well as limited generalisability.

In general, thromboprophylaxis for medical inpatients remains controversial since the number needed to treat to prevent symptomatic VTE ($\approx 1:250-300$) is similar to the number needed to harm to cause major haemorrhage, translating into little or no net overall benefit for patients. In addition, LMH as thromboprophylaxis has never been shown to reduce risk of death in medical patients with other serious infections.

Despite the limitations in the evidence currently available, the International Society for Thrombosis and Haemostasis (ISTH) recently published interim guidelines suggesting to prophylactically treat all hospitalised COVID-19 patients with high-dose low-molecular weight heparin regardless of underlying risk factors for VTE.

In order to guide physicians and policy-makers on this difficult balance between preventing VTE without unacceptable risks of major haemorrhage, we propose to first determine the risk of VTE and major haemorrhagic complications in patients with confirmed COVID-19 and matched control populations, and next, if possible, examine risk factors for VTE.

Priority

The research project will examine an acute research question with limited pre-existing evidence. We believe these urgently needed results may be of significant use for evaluations on use of prophylactic thromboprophylaxis in short-term management of COVID-19 patients and may provide further insights into risk groups.

Research group

This project is proposed by infectious diseases specialists experienced in epidemiological research from four departments of infectious diseases in Denmark. We believe that a close collaboration with the Expert Group under the auspices of the Danish Medicines Agency will ensure the necessary infrastructure as well as outstanding epidemiological and statistical insights to carry out the study. We also welcome collaboration with researchers from other specialties if the Steering Committee should find it relevant.

Conflicts of interests

All researchers from the infectious diseases specialty report no conflicts of interests. If the Steering Committee is in favour of our study proposal, a statement of conflicts of interests from other involved researchers will be submitted as soon as possible.