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COVID STEROID 2 newsletter – March 2021

Status

We are now more than two-thirds into the trial with **670 patients** randomised at **15 Danish sites**, **12 Indian sites**, **2 Swedish sites** and **1 Swiss site**. We are again observing an increase in the recruitment rate, particularly in India and Sweden.

Top recruiters

Congratulations to the Department of Infectious Diseases at Hvidovre Hospital in Denmark for once again being top recruiters of the trial. Amazing work!

Also, congratulations and a big thank you to S. L. Raheja Fortis Hospital in Mumbai, India, for being top recruiters in February 2021.





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Important information

Interim analysis

The data set for the interim analysis was sent to Independent Data Monitoring and Safety Committee (IDMSC) on March 9, 2021. The IDMSC is formed by clinician Christian Hassager (Professor in cardiology, Rigshospitalet, University of Copenhagen, DK), trialist Manu Shankar-Hari (Clinician Scientist, Reader and Consultant in Intensive Care Medicine, National Institute for Health Research and Kings College, London, UK) and biostatistician Susanne Rosthøj (Department of Biostatistics, University of Copenhagen). Baseline data and core outcomes in the whole population have been posted on the [webpage](#) (only the IDMSC sees the data by allocation group). We are very excited to read the recommendations from the IDMSC, and we will arrange investigator meetings after the interim analysis to inform you about these.

Serious adverse events

We kindly remind you again to please note the [new procedure](#) for reporting serious adverse events. Remember to report all events that are either related to the trial intervention or unexpected to sponsor (covid-steroid@cric.nu) within 24 hours of occurrence.

180-day follow-up

180-day follow-up have now commenced for the first patients randomised in the trial. We will assess mortality and health-related quality of life (HRQoL) blinded to the allocation by phone at 180 days after randomisation. Please strive to reach the patients for up to 4 weeks after 180-days follow-up date. We have uploaded [EQ-5D-5L questionnaires](#) in different languages on the website. If you need questionnaires in other languages than the ones uploaded, please request this by contacting covid-steroid@cric.nu.

Protocol

The [protocol paper](#) has now been published in Acta Anaesthesiologica Scandinavica.



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Trial documents

All trial-related documents can be found on our [website](#), and all updates to the Trial Master File can be found [here](#).

Contact

You can reach us at covid-steroid@cric.nu or +45 3545 7237 (available 24/7). Please archive this newsletter in your Site Master File.

A big thank you from Denmark,

Marie, Maj-Brit and Anders