COVID

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COVID STEROID 2 newsletter – June 2021

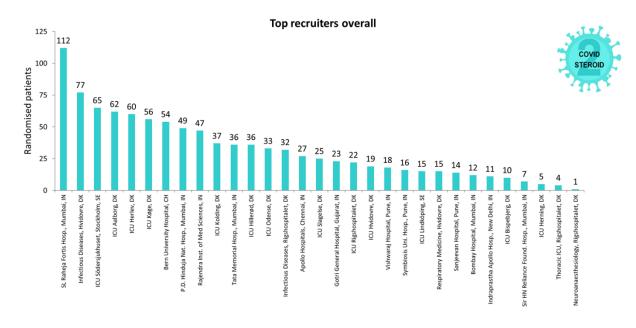
Status

On May 20, **1000** patients had been recruited in the COVID STEROID 2 trial. We are so proud to get here in less than 9 months and we want to say a huge thanks to all participants, relatives, and investigators who have contributed to the trial!

Top recruiters

The top recruiting site was SL Raheja Fortis Hospital in Mumbai, India, who have randomised more than 10% of all patients. Congratulations and thank you for all your hard work during challenging times in India!

Also, a big congratulations to the Department of Infectious Diseases at Hvidovre Hospital in Denmark and Södersjukhuset in Stockholm in Sweden for recruiting the second and third most patients.





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Important information

Trial completion

We ask you to **complete all outcome forms up to day 28 by June 18** at the latest. We expect to lock the database by **June 21**.

We ask you to **complete all baseline forms by June 7 at the latest,** so that we can start analysing baseline data the upcoming week.

We plan to analyse the outcome data at day 28 in the end of June and to submit the manuscript to New England Journal of Medicine in the beginning of July. We plan for a secondary publication on 90-day and 180-day outcomes, when 180-day follow-up have been completed for all patients.

Manuel collection of data

We are currently performing central monitoring of data, including manuel collection of missing data on serious adverse events (SAEs), missing dayforms and other missing values. We have already sent out some data requests and will send out one final request after June 18.

Future correspondences

The coordinating investigator Marie W. Munch is expecting and will go on maternity leave from June 11. Please direct all correspondences after this date to covid-steroid@cric.nu.

Health-Related Quality of Life

HRQoL should be assessed within 4 weeks from the date of 180-day follow-up. If data has not been entered within 4 weeks, the form will lock, and the patient will have missing data on HRQoL.

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Trial documents

All trial-related documents can be found on our <u>website</u>, and all updates to the Trial Master File can be found <u>here</u>.

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.

Thank you and stay safe,

Marie, Maj-Brit and Anders