



Place in Site Master File #13

COVID STEROID 2 newsletter – February 2021

Dear friends – the COVID STEROID 2 trial is more than halfway!

Status

We are now more than halfway in the trial with **550 patients** randomised at **14 Danish sites**, **11 Indian sites**, **2 Swedish sites** and **1 Swiss site**. The last months have been very busy: **204 patients** were randomised in December and **178 patients** in January. We are deeply impressed and grateful for all your hard efforts. Thanks a lot!

New trial sites

Welcome to Gotri General Hospital in Gujarat, India, and Herning ICU in Denmark, that have both randomised their first patients. Thanks so much!

Also, a warm welcome to Klaus V. Marcussen, who will be the new primary investigator at Slagelse ICU, Denmark, and a big thanks to Anders Møller for your work with the trial until now.

Top recruiters

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





Place in Site Master File #13

Important information

Interim analysis

Patient no. 500 was randomised at Slagelse ICU in Denmark on January 24, 2021. All patients randomised up until January 24 will be included in our upcoming interim analysis. The interim analysis will be conducted by an independent Data Monitoring and Safety Committee who will meet when 28-day follow-up data of 500 participants (50% of sample size) have been obtained.

Please ensure to complete data entry in dayforms and 28-day follow-up forms for all patients randomised before January 24 by February 22 at the latest.

For patients discharged to a non-participating department within 14 days of randomisation, data in dayforms will be missing. You will be asked to fill out a data extraction form for these patients. We will send out further information this week.

We will arrange investigator meetings after the interim analysis to inform you about the recommendations from this.

Serious adverse events

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.

Protocol

The protocol paper has now been accepted for publication in Acta Anaesthesiologica Scandinavica.

To the Danish investigators

A new [protocol](#), [EudraCT](#) and approvals from the [Danish Medicines Agency](#) and [Health Research Ethics](#) have been uploaded to the website. Please print these and place in your SMF.

Trial documents

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



Place in Site Master File #13

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