

# Place in Site Master File #13f

# HOT-COVID newsletter – November 2020

Status

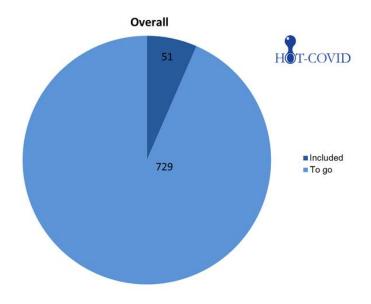
Dear friends and colleagues

We are happy to present this first newsletter for the HOT-COVID trial.

The HOT-COVID trial, which is an amendment to the HOT-ICU trial, but only including COVID-19 positive for SARS-CoV-2 was launched shortly after completed recruitment in the HOT-ICU trial. All trial related procedures and interventions are the same in the HOT-COVID as in the HOT-ICU trial, and thus will all trial relevant documents be available on both the HOT-ICU and the HOT-COVID <u>website</u>.

## Recruitment

On August 25<sup>th</sup> the first patient was enrolled in the HOT-COVID trial at Herlev Hospital. By now 51 patients have been recruited! We have initiated the trial in 8 Danish sites, in Basel (Switzerland) and Oslo (Norway), and hope to start soon in Iceland and the UK.



### **Consent forms:**

We have implemented the possibility to upload all consent documents to the eCRF using the *consent form*. All sites are welcome to use this feature, but please note that it is only **mandatory for Danish sites**.

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#### Things to highlight:

- 1. Please strive to screen all patients fulfilling the inclusion criteria as soon as possible after ICU admission
- 2. Please ensure that the specific e-mail notifications of major protocol violations are handled to secure adherence to protocol for all patients
- 3. Please use the "Consent form" in the eCRF to upload all relevant consents
- 4. The following documents have been updated: <u>HOT-COVID protocol 1.2</u> <u>Approval form the Ethics Committee</u> of the HOT-COVID protocol 1.2 (in Danish) <u>Approval from the Danish Medicines Agency</u> of the HOT-ICU protocol 2.2 (in Danish) <u>HOTCOVID co-enrolment form version 1.2</u> with approval for co-enrolment in the COVIPOC, COVID STEROID 2, and GODIF trials <u>Approval for extension of data registration</u> (in Danish) <u>GCP Monitoring and Data verification plan version</u> 3.0 (in Danish)

#### HOT-COVID hotline

If you have any questions do not hesitate to send an e-mail to <u>hot-covid@cric.nu</u> or to contact the HOT-COVID hotline (+45 2118 2543). Please **leave a message and your phone number if the call is not answered** and we will call you back as soon as possible.

Please archive this newsletter in your site master file.

Kindest regards, Thomas, Olav and Bodil



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