

## Place in Site Master File #13f

#### **HOT-ICU** newsletter – June 2020

Thank you very much for your steady commitment to the HOT-ICU trial.

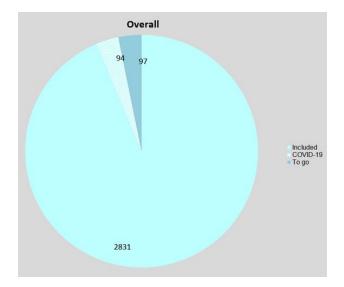
#### **Status**

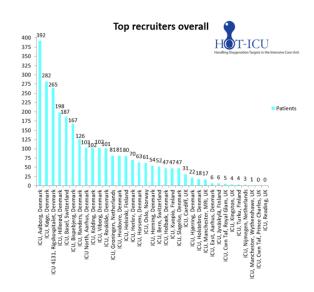
There is now less than 100 patients to go before trial completion! Fantastic work effort by all participating sites!

We urge all sites to both submit old dayforms, and continuously enter data from new dayforms in the eCRF.

Basel included patient number 2828 on the 6<sup>th</sup> of June, marking the remaining 100 patients in the trial. Congratulations to the site. They will receive a prize for their effort. The site that includes the last patient will also be rewarded.

Reykjavik has joined the trial and have included their first patient! We wish our North Atlantic colleagues a very warm welcome.







#### Top recruiters

Top recruiters in May were:

- **1.** Aalborg (12)
- 2. Department 4131 (9)
- **3.** Køge (9)
- 4. Basel (7)
- 5. Slagelse (7)

Congratulation to all sites!

#### 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
- The following documents have been updated:
   <u>Approval from ethics committee (amendments numbers 6 + 7)</u> (in Danish). Approval of extension of the HOT-ICU trial until December 31<sup>st</sup> 2021, and approval of the HOT-COVID trial as an addition to the HOT-ICU trial.
- 4. **ONLY DANISH SITES:** The eCRF has been updated with an added <u>optional</u> consent form. May be used if appropriate; e.g. when transferring patients between sites.

### Keep up the great work!

If you have any questions, do not hesitate to send an e-mail to <a href="https://hot-icu@cric.nu">hot-icu@cric.nu</a> or to contact the HOT-ICU 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 to all of our fantastic colleagues at all participating sites, Thomas, Olav and Bodil







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