



Place in Site Master File #13f

HOT-ICU newsletter – May 2019

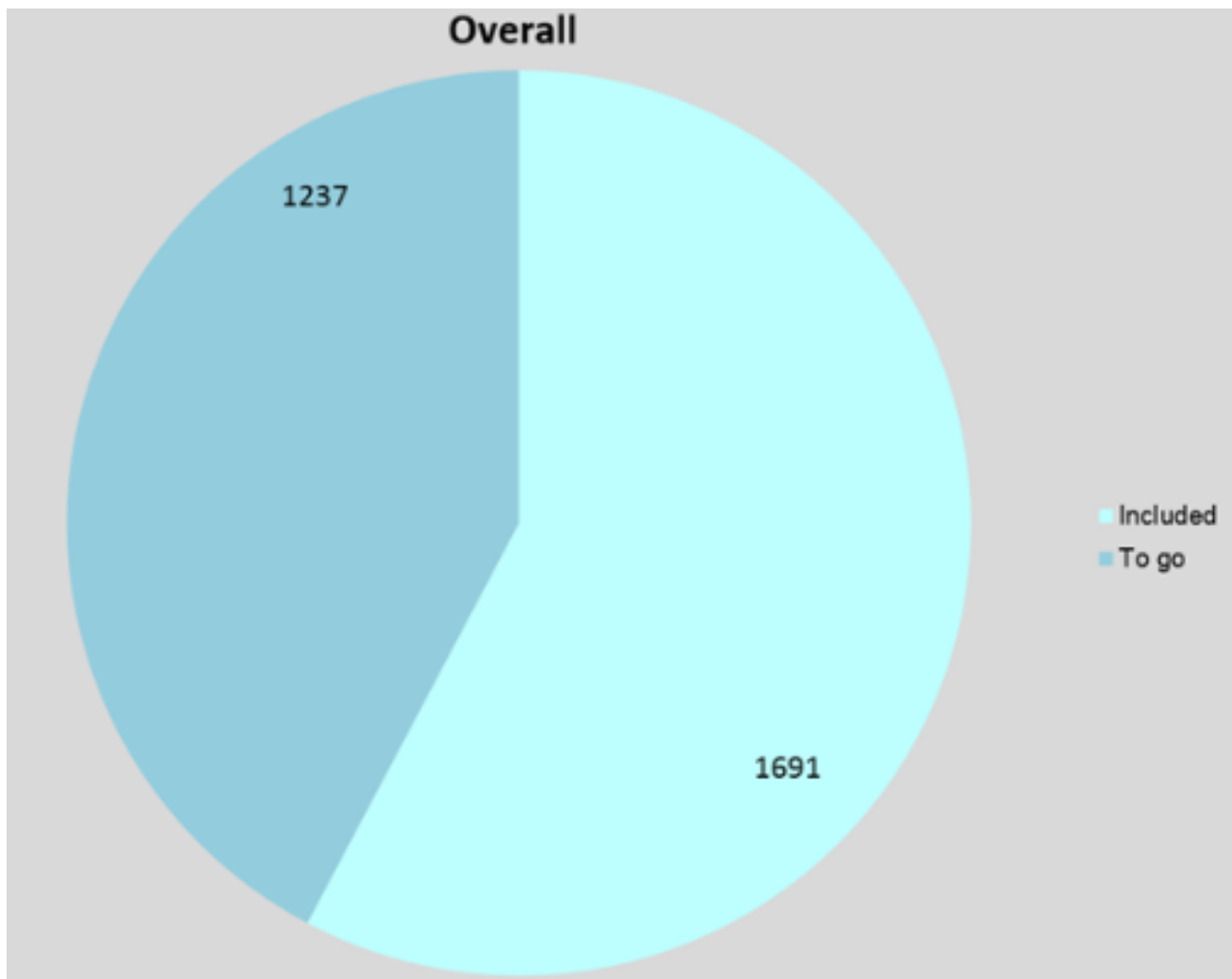
Thank you very much for your steady commitment to the HOT-ICU trial.

Status

By May 1, 2019, Thomas Lass Klitgaard, MD is the new coordinating investigator in the HOT-ICU trial as well as PhD student with focus on long-term outcomes in the trial. Olav Lilleholt Schjørring, MD has submitted his PhD Thesis and will start as staff specialist in our Department of Anaesthesia and Intensive Care Medicine, but will continue part-time (one day per week) as post-doc affiliated to the HOT-ICU trial.

With the upcoming interim analyses we urge all sites to enter data on patients up until March 3rd 2019.

The study is progressing steadily with a total of 1691 patients enrolled.



Top recruiters

Top five recruiters in April were:

1. Afd. 4131, Copenhagen (11)
2. Helsinki (10)
3. Aalborg (10)
4. ICU North, Aarhus (8)
5. Bispebjerg (5)

Congratulation to all sites.

Things to highlight:

1. We are now nearing the planned interim analysis at follow-up day 90 of patient number 1464. **Please ensure that all data on every patient randomised up until March the 3rd 2019 are entered into the system within June 2nd 2019.**

As usual:

2. Please strive to screen all patients fulfilling the inclusion criteria as soon as possible after ICU admission
3. Please ensure that the specific e-mail notifications of major protocol violations are handled
4. Please check the site master file log (<http://www.cric.nu/hot-icu-log-for-site-master-file/>) regularly for updates
5. For Danish sites: A new version of the document "*Forsøgspersoners rettigheder...*" has been uploaded to the website: <http://www.cric.nu/hot-icu-forsogspersoners-rettigheder/>. Please ensure that henceforth, this is the version of the document, which is distributed with the information material to trial participants, next-of-kins, and trial guardians

If you have any questions, do not hesitate to send an e-mail to hot-icu@cric.nu 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.

Best regards

Thomas, Bodil and Olav