



## Place in Site Master File #13f

### HOT-ICU newsletter – July 2019

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

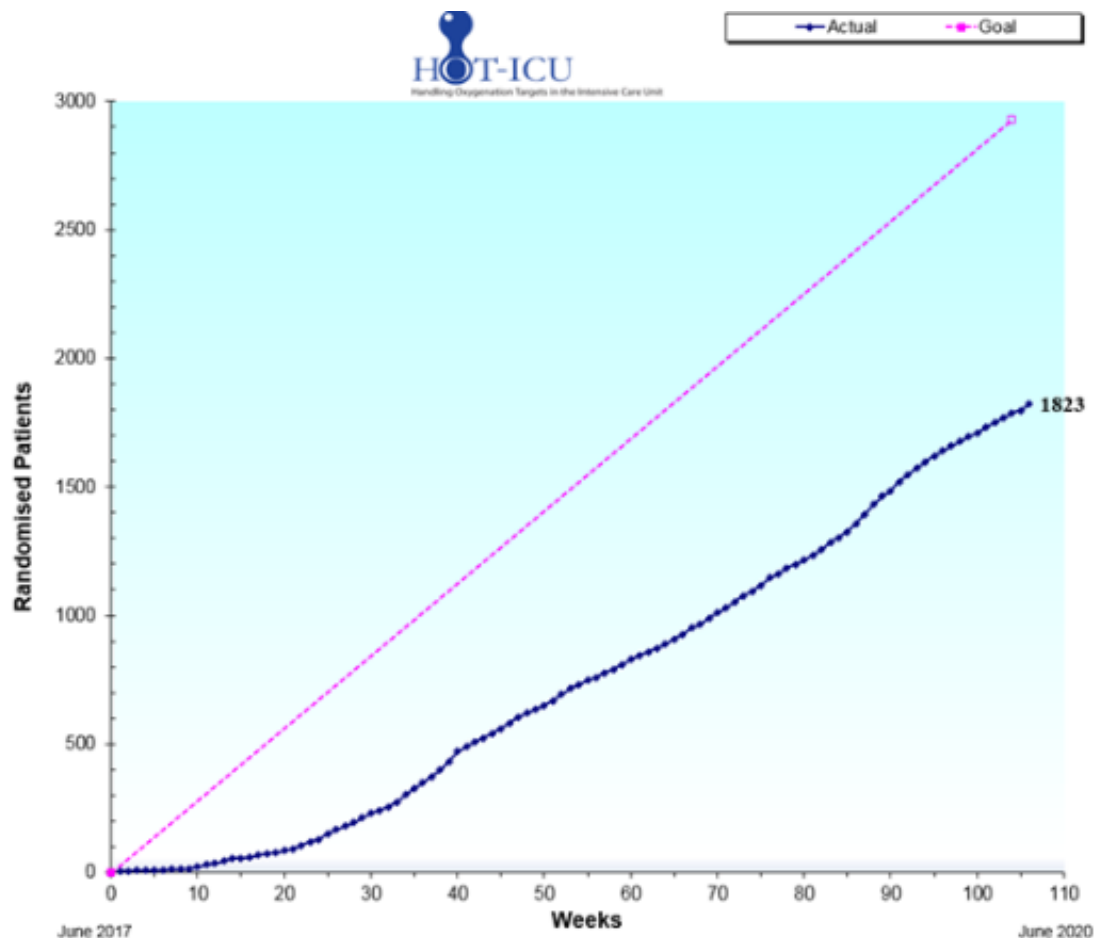
#### Status

Cardiff has now started, and has already included three patients. More UK sites are expected to participate in the trial.

We urge all sites to keep up the good work with screening and including all potential patients for the trial. We still have some way to go.

Data on the first 1464 patients has been sent to the Data Monitoring and Safety Committee for review.

The study is progressing steadily with a total of 1823 patients enrolled.



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## Top recruiters

Top five recruiters in June were:

1. Aalborg (10)
2. Roskilde (9)
3. Afd. 4131 Rigshospitalet (6)
4. Køge (6)
5. Basel (5)

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.
3. Please check the site master file log (<http://www.cric.nu/hot-icu-log-for-site-master-file/>) regularly for updates.
4. For Danish Sites: A new version of the document "*Monitoreringsplan*" has been uploaded to the website: <http://www.cric.nu/hot-icu-monitoring-and-data-verification-plan/>. Please print and place in the Site Master File.

We wish all of you a great summer!

If you have any questions, do not hesitate to send an e-mail to [hot-icu@cric.nu](mailto: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, Olav and Bodil

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