



## Place in Site Master File #13f

### HOT-ICU newsletter – September 2019

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

#### Status

The pre-planned interim analysis of the first 1.464 patients has been conducted and the blinded results has been assessed by the Data Monitoring and Safety Committee, which recommends that the HOT-ICU trial continues, as no evident harms has been detected.

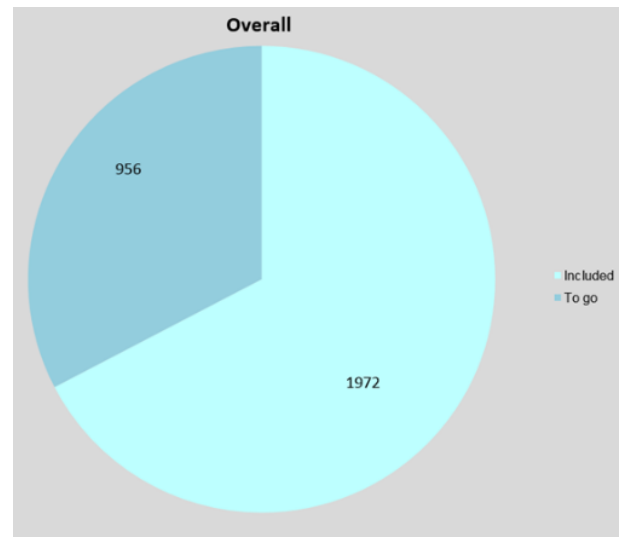
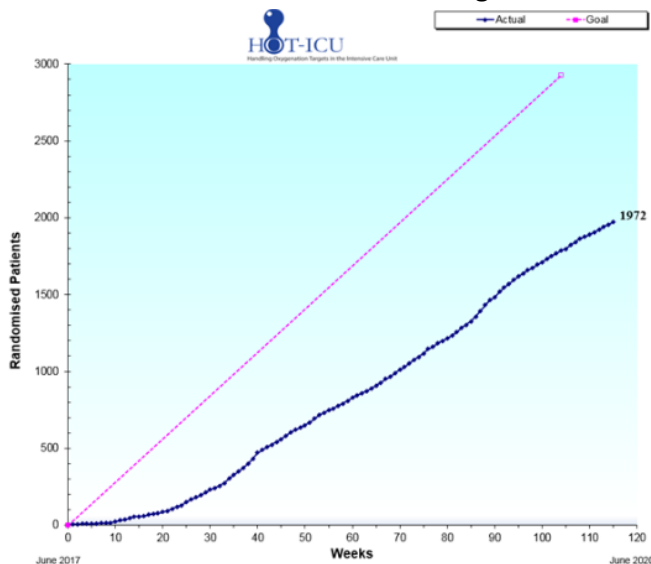
Since the last newsletter, UK have joined the trial. Congratulation to Cardiff with nine patients included so far. Additionally three new UK sites will soon take part in the study.

The study is progressing steadily and a new landmark is approaching – inclusion of patient number 2.000. The site who includes patient # 2.000 will be rewarded, as Kolding Hospital was rewarded when they included patient #1.000.

Who will be the next? There is still 38 patients to go 😊!



#### Progress so far with 1972 included patients:



## Top recruiters

Top five recruiters in July and August were:

1. **Køge (21)**
2. **Aalborg (19)**
3. **Afd. 4131 Rigshospitalet (9)**
4. **Bispebjerg (6)**
5. **Hillerød (6)**

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. New versions of "[HOT-ICU Contact details](#)" and "[Annual Safety Report](#)" have been uploaded to the webpage. Please print and place in Site Master File
5. A new version of "[Steering Committee](#)" has been uploaded to the webpage

We hope all of you have had a wonderful 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.

Kindest regards

Thomas, Olav and Bodil

