





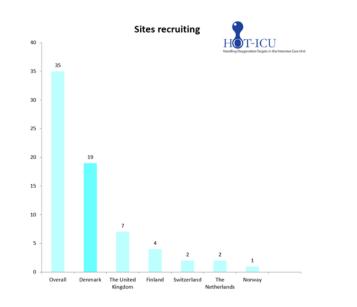
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HOT-ICU newsletter - December 2019

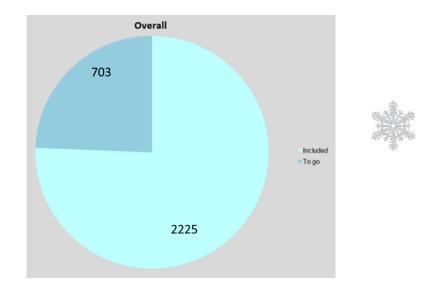
Thank you very much for your steady commitment to the HOT-ICU trial.

Status

We are very proud of this great international collaboration with a total of 35 sites now participating! Recently, the UK has become a part of the trial with seven sites, of which two sites are awaiting the final approval to include patients.



We have now passed the 75% mark of the inclusions in trial with patient number 2196 being included on the 26th of November in Kolding. In total 2225 patients are now randomised, thus we still have 703 to go.



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Top recruiters

Top five recruiters in November were:

- **1.** Køge (8)
- 2. ICU North, Aarhus (7)
- **3.** Randers (7)
- **4.** Aalborg (7)
- **5.** Afd. 4131, Copenhagen (6)

Congratulation to all sites!



Things to highlight:

- 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. The documents following have been updated:
 <u>Trial Protocol</u>, <u>EudraCT-form</u>, approvals from the <u>Danish Medicines Agency</u> and <u>Ethics Committee</u> (in Danish), the <u>Monitoring plan</u> is updated with the <u>first addendum to version 2</u> (in Danish), the <u>Data verification</u> plan is updated to <u>version 7</u>, and the <u>Co-enrolment list</u> (version 10.0) with the addition of the ADAPT-Sepsis Trial

Please print and file in Site Master File

Keep up the great work!

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.



We wish you all a very merry Christmas and a happy New Year!









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