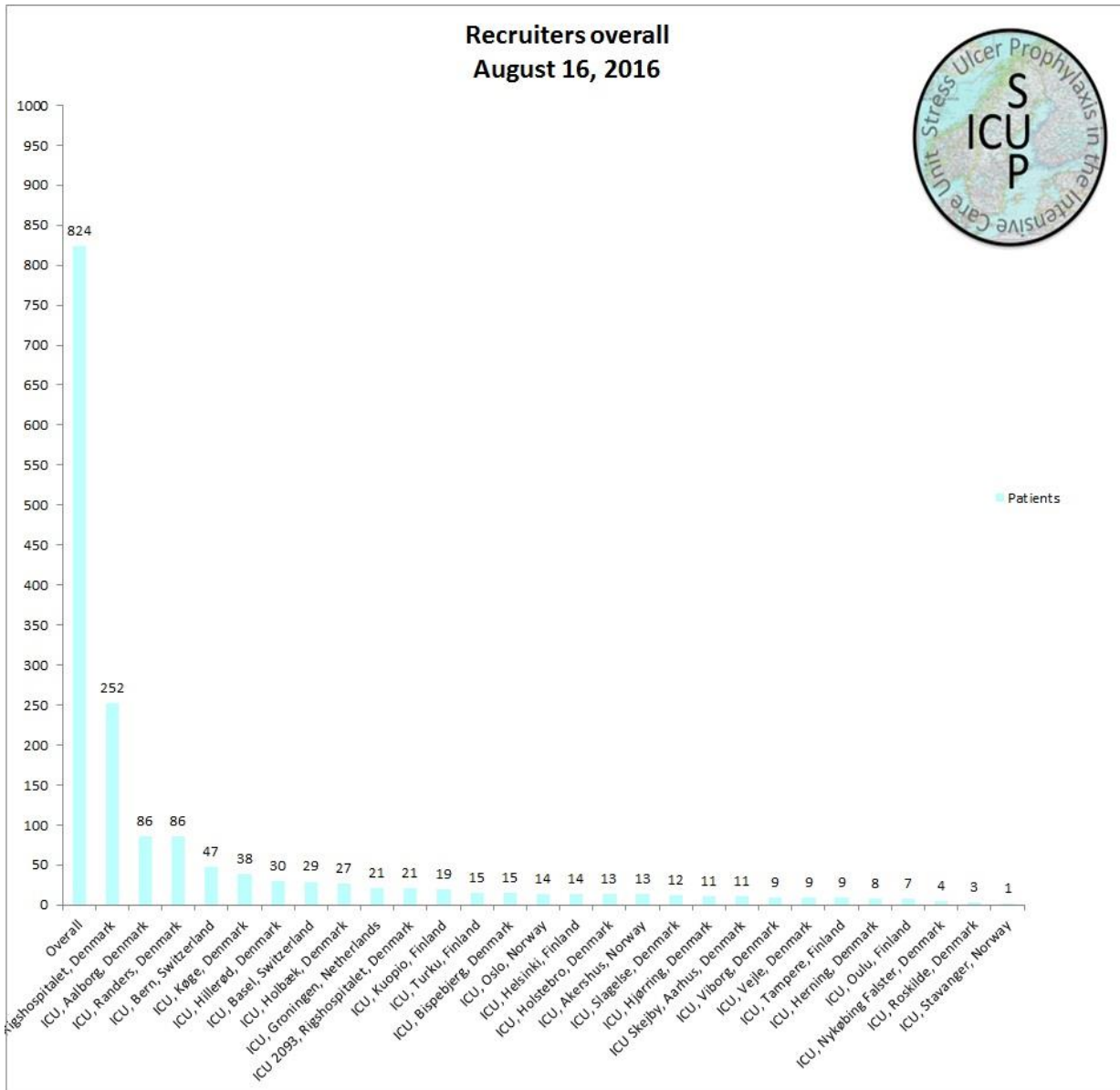




Place in Site Master File #13

SUP-ICU newsletter – August 2016

Thank you for your great commitment to the SUP-ICU trial.



Status

Since the previous newsletter around 178 patients have been randomised, and we have now randomised 824 patients (24%). Twenty-eight sites in five countries are active. Well done and thanks to all of you for the effort.

You can follow the inclusion and the number of active trial sites at www.sup-icu.com (press F5 to refresh the page and get the updated status).

New sites

In July Groningen (Netherlands) started recruiting patients along with Roskilde and Nykøbing Falster (DK). Recently, Stavanger (Norway) has joined - a very warm welcome to you all in SUP-ICU!

Top recruiters

Top 5 overall recruiters in July were:

1. Bern (19)
2. Basel (18)
3. Aalborg (12)
4. Groningen (11)
5. Rigshospitalet 4131 (11)

Congratulations to Bern and Basel for keeping up a very impressive inclusion rate during the summer – a tremendous contribution to the trial!

Groningen has been off to an excellent start with 21 included patients since joining the team mid-July, including several weeks as top 1 recruiter!

Future active sites

Coming up is the anticipated inclusion of UK sites (5-10) in SUP-ICU – currently we are awaiting the final national approvals.

Important information

- 1) The previous 6-8 weeks the inclusion rate has dropped (probably due to holidays). In order to be able to finish within the scheduled 2 years, we need to increase the inclusion rate, so please systematically screen patients for inclusion. Thanks!
- 2) When a SUP-ICU patient is readmitted to the ICU, please remember to continue the trial intervention with the first dose administered at the time of readmission and the following doses at the usual time of administration on your given site.
- 3) We have added the first Annual Safety Report as #4. (<http://www.cric.nu/sup-icu-annual-safety-report/>) in the Site Master File, and Table of Content has therefore been updated (<http://www.cric.nu/table-of-content/>). Please, print and add in your printed version of the Site Master File.

Other

Anders Granholm and Carl Anthon – both pre-graduate research scholars (medical students) - will join the SUP-ICU team from September 1st.

SUP-ICU hotline

If you have any questions please send us an email (soeren.marker.jensen.01@regionh.dk) or contact the SUP-ICU hotline 24/7 (+45 3545 7450). If no one answers the phone, please **leave a message and your phone number** and we will call you back as soon as possible.

Please archive this newsletter in your Site Master File.

Best regards

Søren, Tine, Mette and Morten