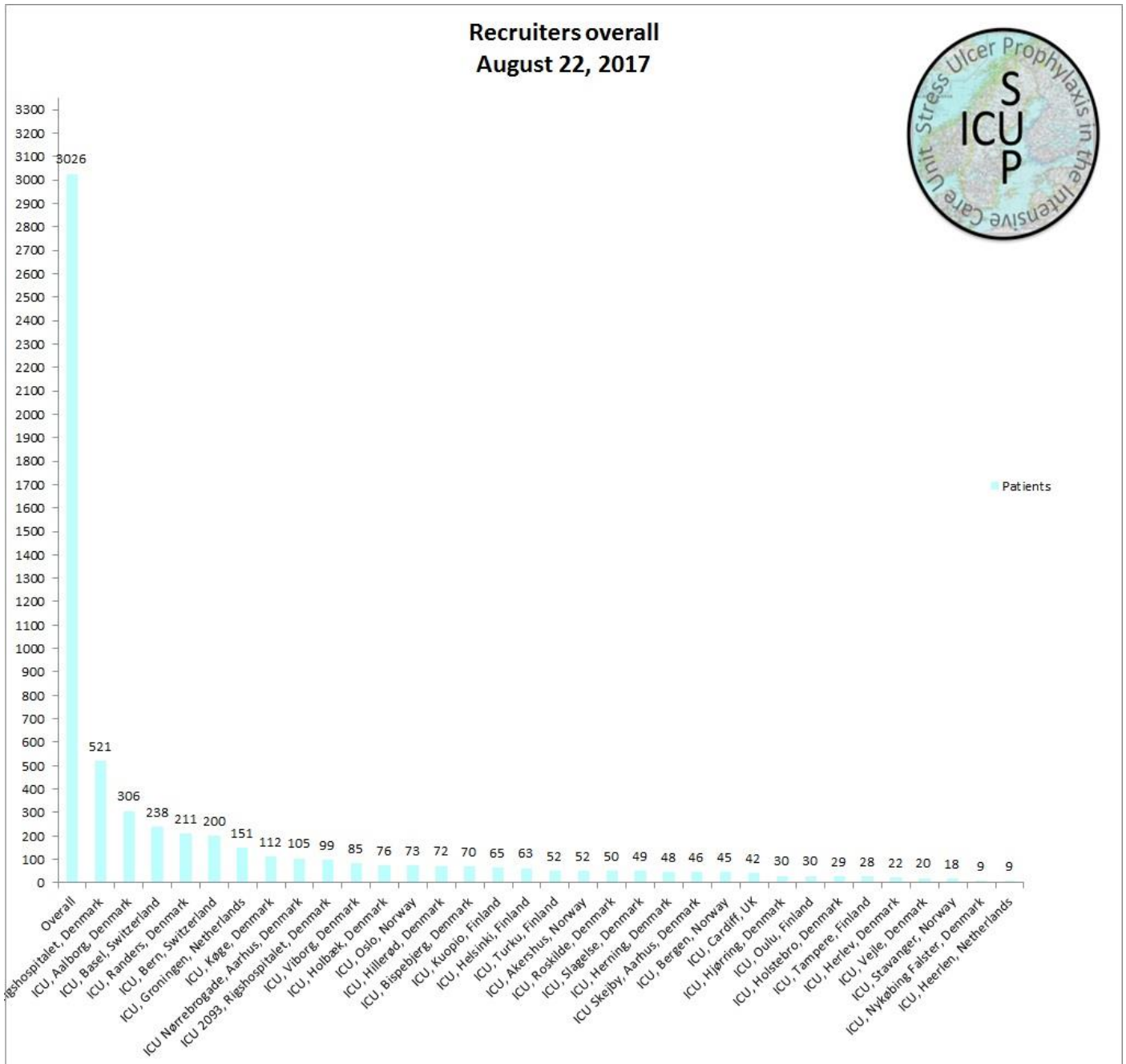




Place in Site Master File #13

SUP-ICU newsletter – August 2017



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



Status

We hope that you all have had a wonderful summer holidays!

Since the previous newsletter more than 210 patients have been randomised, and we have now randomised 3021 patients (90%). Thirty-one sites in six countries are active.

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).

Site changes

- *Nykøbing Falster Hospital (DK) and Roskilde Hospital (DK)* are no longer active in the trial.

Top recruiters

Top 5 overall recruiters in July were:

1. (Rigshospitalet 4131) (24)
2. Basel (15)
3. Aalborg (14)
4. Rigshospitalet 2093(9)
5. Bern (9)

Congratulations to Basel for finishing as monthly top recruiter in July!

Aalborg, Rigshospitalet 2093 (Neuro ICU) and Bern continue to randomise patients at a steady state.

Important information

- **As previously mentioned trial medication will expire end of november 2017, why we need to randomise the last patient as close as possible to September 1st 2017 to maximize the number of days of follow-up with IMP.** The trial will continue until 3350 patients have been randomised.
- **The 1-year follow-up feature has been implemented in the eCRF** – this form will automatically appear among the patient's forms 365 days post-randomisation. Please fill in the information needed when possible.
- **An amendment to Appendix 3 (charter of the DMSC) of the protocol has been approved by the danish authorities (<http://www.cric.nu/sup-icu-appendix-3/>)** – please print and archive in your respective Site Master File #1. **Extended approvals (in Danish) from the Danish Ethics Committee (<http://www.cric.nu/ethic-committee-danish/>) and Danish Health Authority (<http://www.cric.nu/the-danish-health-and-medicines-authority-danish/>)** has been granted– please print and archive in your respective Site Master File #4.

Other

- Thank you very much for your commitment; keep up the good work – less than 10% to go!

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.

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Please continue to systematically screen patients for inclusion, as a big combined effort is needed to finish the trial in time. Please keep the spirit high – you are all doing a tremendous work.

Please archive this newsletter in your Site Master File.

Best regards

Søren, Anders, Carl and Morten