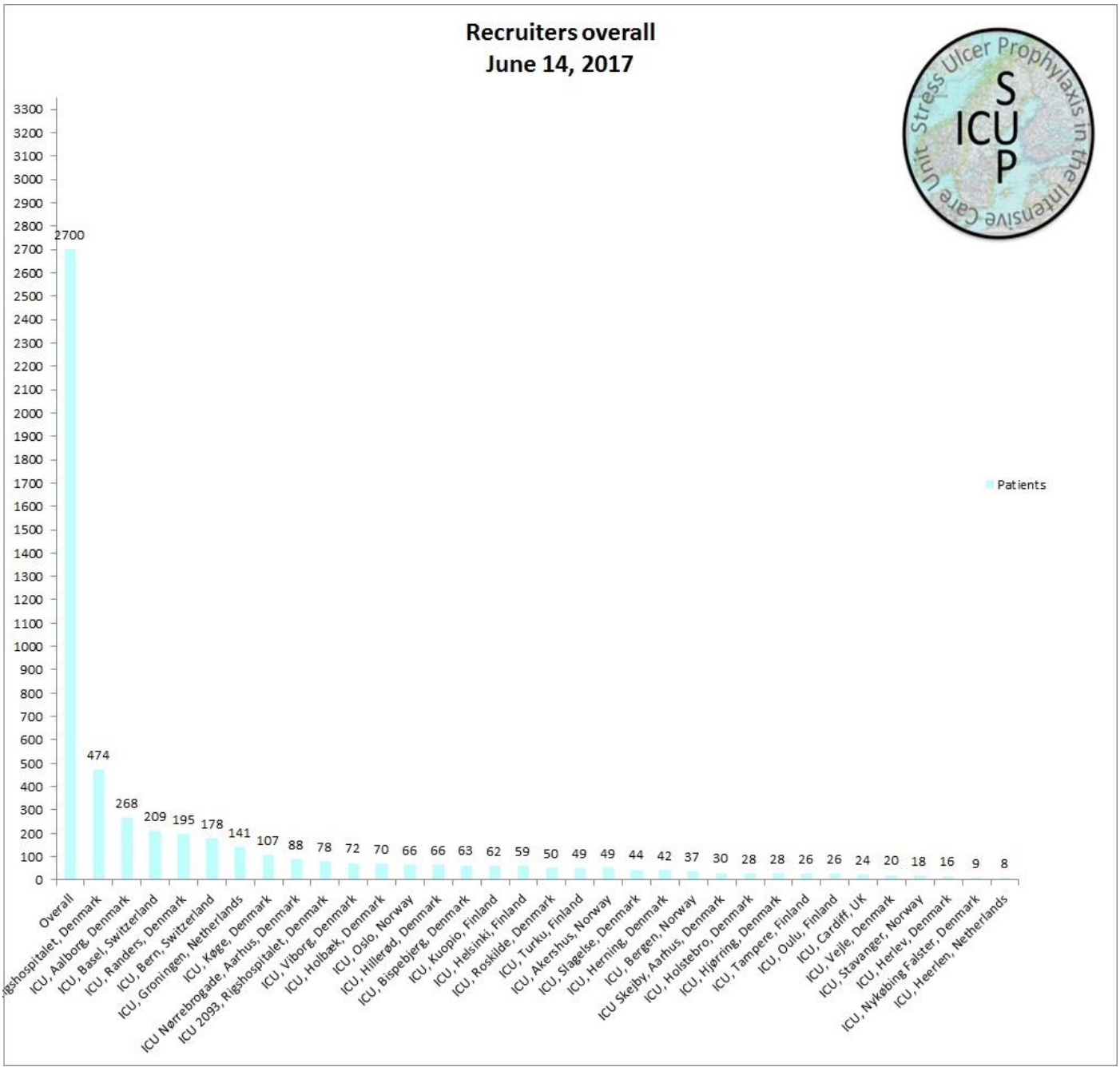
Place in Site Master File #13

SUP-ICU newsletter – June 2017



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

Status

The first interim analysis has been conducted and the blinded results have been assessed by the Data Monitoring and Safety Committee, which recommends that SUP-ICU continues, as no evident harm has been detected. . Furthermore, as the results of the second interim analysis will not be available until after completion of the trial (due to the high inclusion rate); it has been decided to cancel the second interim analysis.

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 and an impressing effort!

Since the previous newsletter more than 262 patients have been randomised, and we have now randomised 2700 patients (80%). May has been the best month so far in terms of inclusions – with a new record of 236 included patients! Thirty-two 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

- No new sites has been added since the May newsletter
- *Nykøbing Falster Hospital* (DK) is no longer active in the trial.
- *Roskilde Hospital* (DK) will not be active as from June 18.

Top recruiters

Top 5 overall recruiters in May were:

1. Aarhus NBG (26)
2. (Rigshospitalet 4131) (22)
3. Rigshospitalet 2093 (18)
4. Aalborg (18)
5. Randers (14)

Congratulations to Aarhus NBG for finishing as monthly top recruiter in May – 26 patients included in Aarhus in one month – very impressing! Rigshospitalet 2093 (Neuro ICU), Aalborg and Randers continue to randomise patients at a steady state.

Future active sites

Additional UK sites will hopefully join SUP-ICU. Italian sites are awaiting the final national approvals.

Important information

- **A previously mentioned trial medication will expire end of november 2017, why we need to randomise the last patient before September 1st 2017 to ensure the possibillity of a full 90-day follow-up with IMP. The trial will continue untill 3350 patients have been randomised (even if this exceeds September 1)..**
- *Annual Safety report:* Please find the annual safety report attached to this newsletter and on the website – please archive this in your Site Master File section 4.

- A "*Drug transfer procedure*" and "*Drug transfer form*" has been developed and will be in use for all transfer of IMP from one hospital to another. Specific instructions will be provied by CRIC representative for each IMP transfer.
- *IMP disposal*: Please do not dispose any IMP before the trial has been completed as any surplus IMP (incl. "lonely vials") should be accounted for at the end of the trial. Instructions on IMP disposal using the "drug disposal form" in the Site Master File, will be distributed in due time.

Other

- Thank you very much for your commitment; please keep up the great work – less than 20% 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.

Please archive this newsletter in your Site Master File.

Best regards

Søren, Anders, Carl and Morten