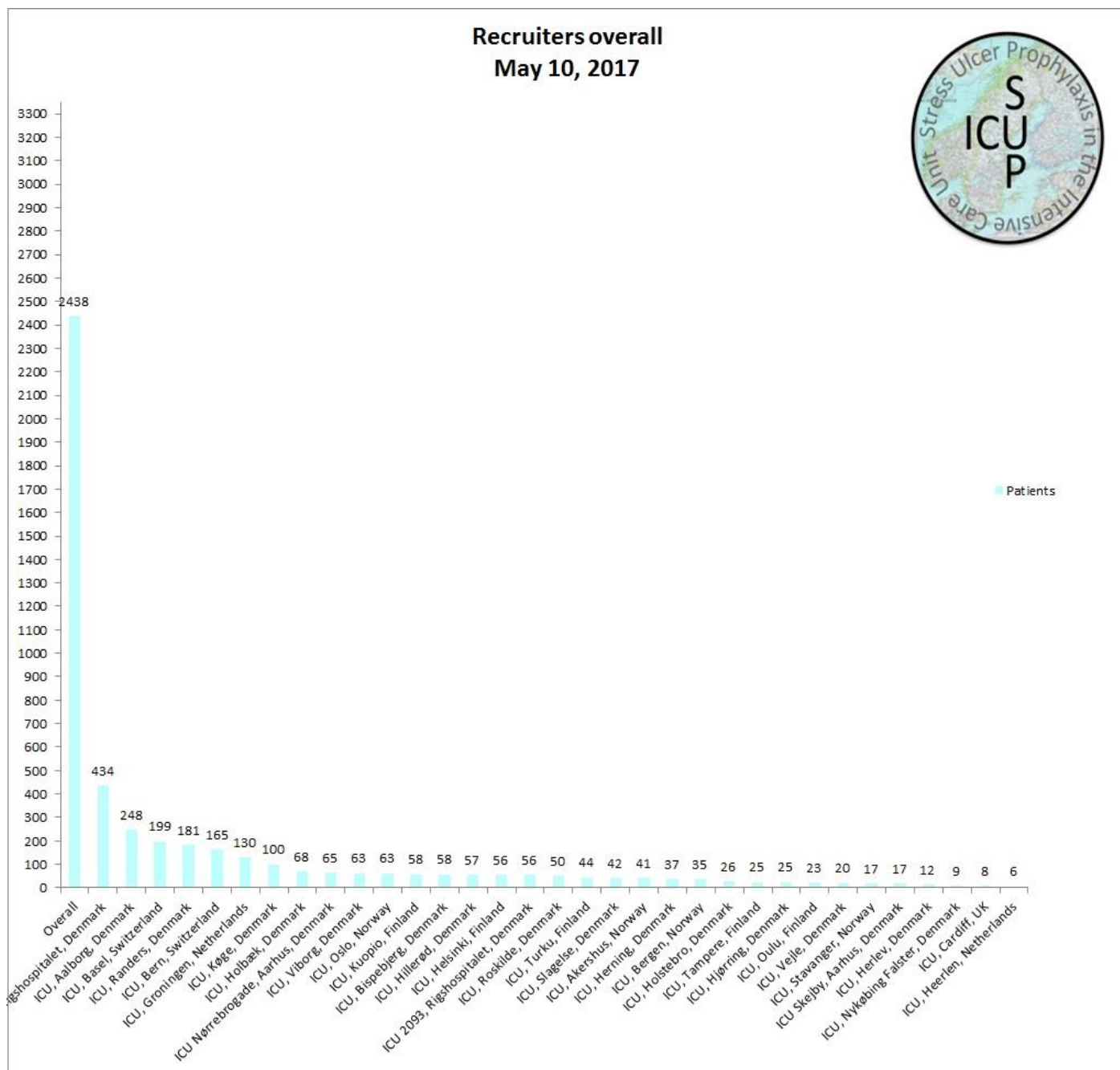




Place in Site Master File #13

SUP-ICU newsletter – May 2017



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



Status

Data for the first interim analysis (1675 patients) has been handed over to the DMSC (Data Monitoring Safety Committee). This is an important milestone in the trial. Results are expected within the next couple of weeks.

We would like to thank each and every one of you for your big work effort in terms of completing data registration and allowing the interim analysis to be completed!

Since the previous newsletter more than 195 patients have been randomised, and we have now randomised 2438 patients (72%). Thirty-three 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).

New sites

Cardiff University Hospital - the first UK site – has joined the trials. A warm welcome in SUP-ICU!

Top recruiters

Top 5 overall recruiters in April were:

1. Basel (27)
2. (Rigshospitalet 4131) (22)
3. Rigshospitalet 2093 (16)
4. Aalborg (15)
5. Randers (13)

Congratulations to Basel for finishing as monthly top recruiter in April – 27 patients included in Basel in one month – a new overall monthly record for a single site! Rigshospitalet 2093 (Neuro ICU), Aalborg and Randers continue to randomise patients at a steady state.

Future active sites

Additional UK sites are expected to join SUP-ICU. Italian sites are awaiting the final national approvals.

Important information

- **Trial medication will expire end of november 2017, why we need to randomise the last patient before September 1st 2017, as explained in the April newsletter. Consequently, we need to include at least 57 patients each week from now on! Please continue to systematically screen patients for inclusion, as a big combined effort is needed to finish the trial in time. Weekly inclusion rate emails will allow you to follow the inclusion rate on a weekly basis. Please keep the spirit high – you are all doing a tremendous and impressive effort!**
- IMP disposal: Please do not dispose any IMP before the trial has ended 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 SMF, will be distributed in due time.
- A lot of ‘unobtainable’-values are still registered in baseline forms. Please take measures to obtain these values, if possible. Local principal investigators will from now on receive automatic email notifications if data

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are missing

Other

- Thank you very much for your commitment; please keep up the great work – less than 30% 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