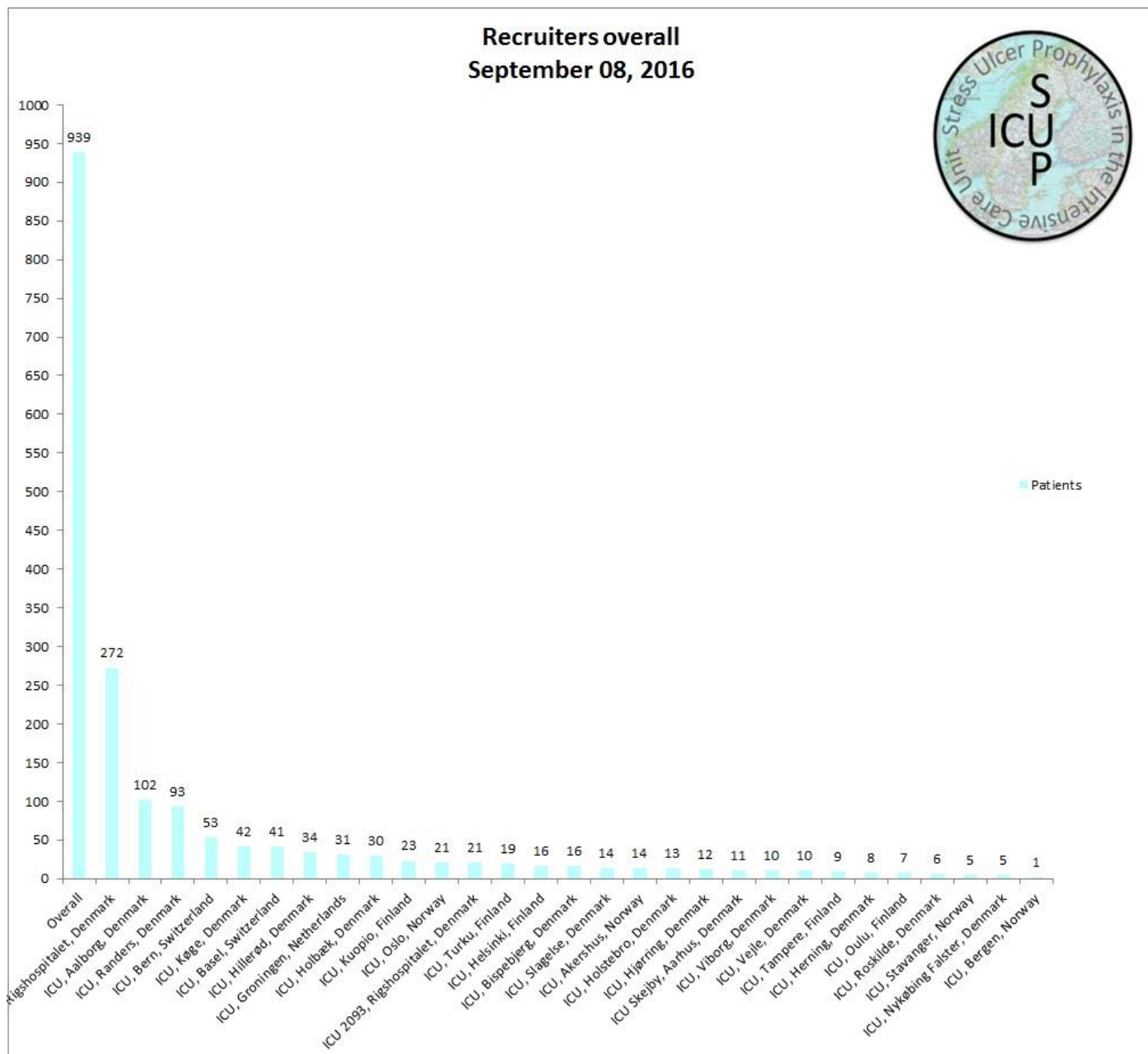




Place in Site Master File #13

SUP-ICU newsletter – September 2016

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



Status

Since the previous newsletter more than 115 patients have been randomised, and we have now randomised 938 patients (28%). Twenty-nine 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

This week Bergen (Norway) randomised the first patient – a warm welcome!

Top recruiters

Top 5 overall recruiters in August were:

1. (Rigshospitalet 4131 (26))
2. Aalborg (19)
3. Groningen (17)
4. Basel (13)
5. Randers (12)

Congratulations to Aalborg on a very impressive inclusion rate in August, and for reaching a landmark **100 randomised patients** in the SUP-ICU trial! (See photo below).

Groningen, Basel and Randers continue to randomise patients at a steady inclusion rate.

Future active sites

Aarhus Nørrebrogade (DK) is expected to start in a short while – we are looking very much forward to welcoming you in the trial.

Some 5-10 sites in UK are expected to join during fall. Currently we are awaiting the final national approvals.

Finally, the inclusion of Italian sites in SUP-ICU has moved closer.

Important information

- 1) It is not possible for you to change data in “screening forms” and “discharge forms”. If you are subject to change data in these forms , e.g. following GCP-monitoring by the relevant authorities, you need to contact the coordinating investigator (soeren.marker.jensen.01@regionh.dk), and our data manager will make the changes for you.

Other

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

The site including patient number 1000 in the SUP-ICU trial will receive 12 bottles of red wine – so keep up the good work!

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.

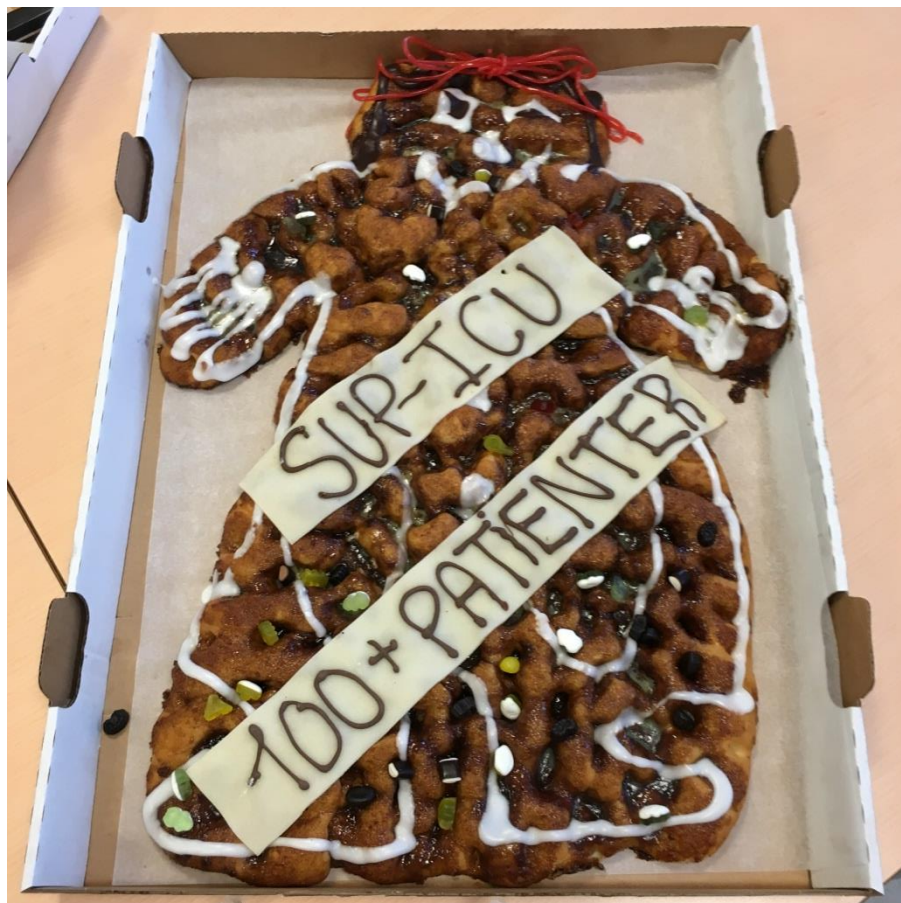


Photo from Aalborg - the celebration of 100+ included patients in SUP-ICU!

Best regards

Søren, Mette, Tine, Anders, Carl and Morten