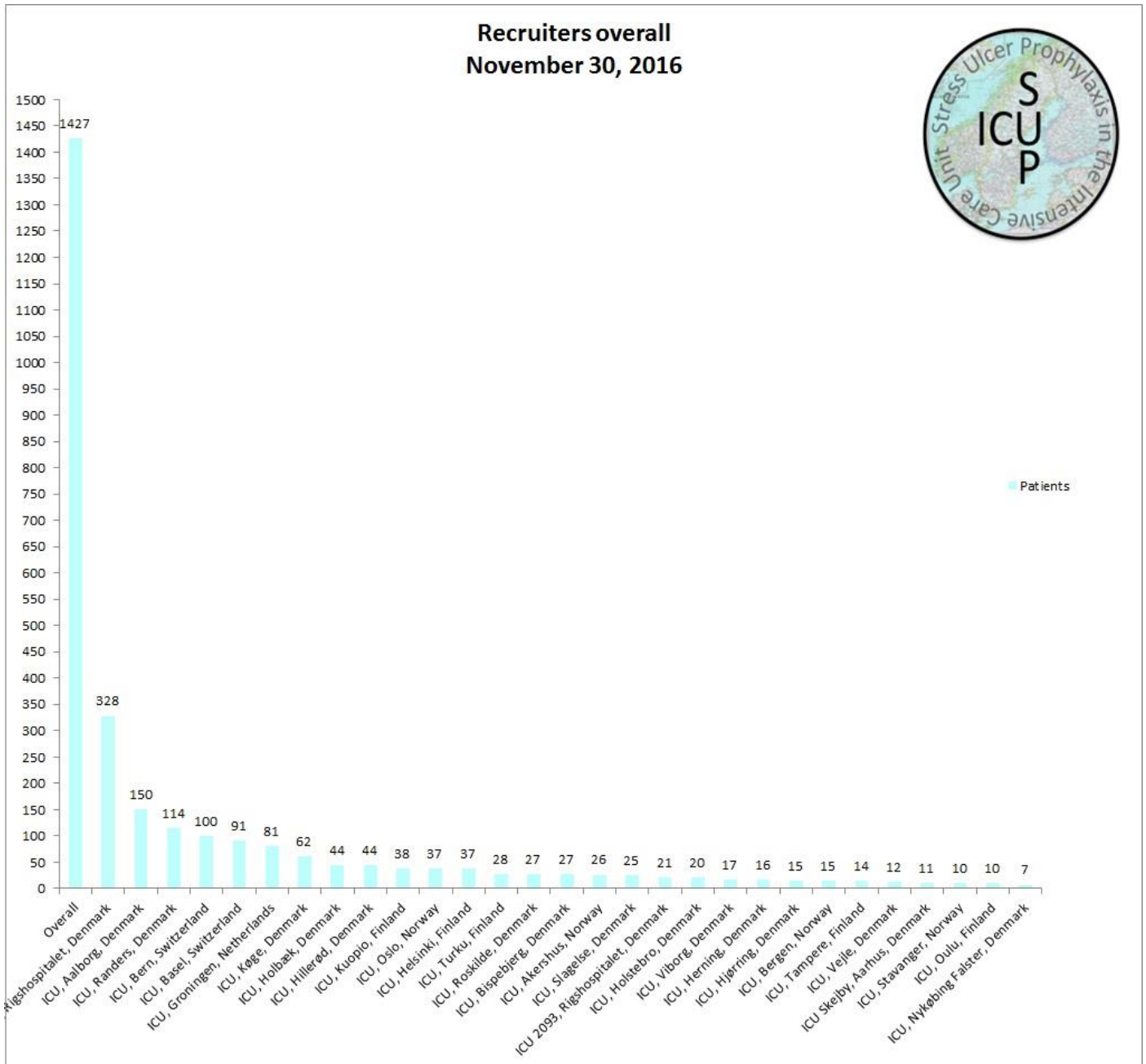




Place in Site Master File #13

SUP-ICU newsletter – December 2016

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



Status

Since the previous newsletter more than 142 patients have been randomised, and we have now randomised 1447 patients (43%). Twenty-nine sites in five 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

No new sites have joined since the last newsletter.

Top recruiters

Top 5 overall recruiters in November were:

1. (Rigshospitalet 4131) (19)
2. Basel (18)
3. Aalborg (17)
4. Bern (15)
5. Groningen (14)

Congratulations to Basel for finishing as the monthly top recruiter!

Future active sites

Aarhus Nørrebrogade (DK) is expected to start very shortly – we are looking very much forward to welcoming you in the trial. UK and Italian sites are expected to join early 2017. Currently we are awaiting the final national approvals.

Important information

- **IMPORTANT:** in order to complete the SUP-ICU trial, we need to redistribute trial medication between sites following the interimanalysis in the spring 2017. The redistribution of trial medication will be done in order to ensure that trial sites have enough trial medication to the active patients, as many sites have/will end up with residual trial medication. Production of additional trial medication is unfortunately not possible. Practically, trial sites will be closed down in a stepwise manner, beginning with the trial site(s) (in each participating country) using the least trial medication. Accordingly, we expect that only few trial sites will be active towards the end of the trial! Additional information will follow in due time.
- **IMPORTANT:** in order to prepare for the forthcoming interimanalysis in spring, we kindly ask you to complete registration of all patients with 90-day follow-up. Following completion, the remaining part of the case-money will be transferred.

Other

- Please welcome Italian Sara Russo Krauss (srk@cric.nu), molecular biologist, who has joined the SUP-ICU team. Sara is a clinical research assistant at CRIC (Centre for Research in Intensive Care), Denmark. She will handle issues in English only, and is responsible for organisational matters, including case-money and up-coming contracts.
- November has been another productive month in SUP-ICU with 175 included patients. Thank you very much for your commitment; please keep up the great work - Less than 2000 patients to go!

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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