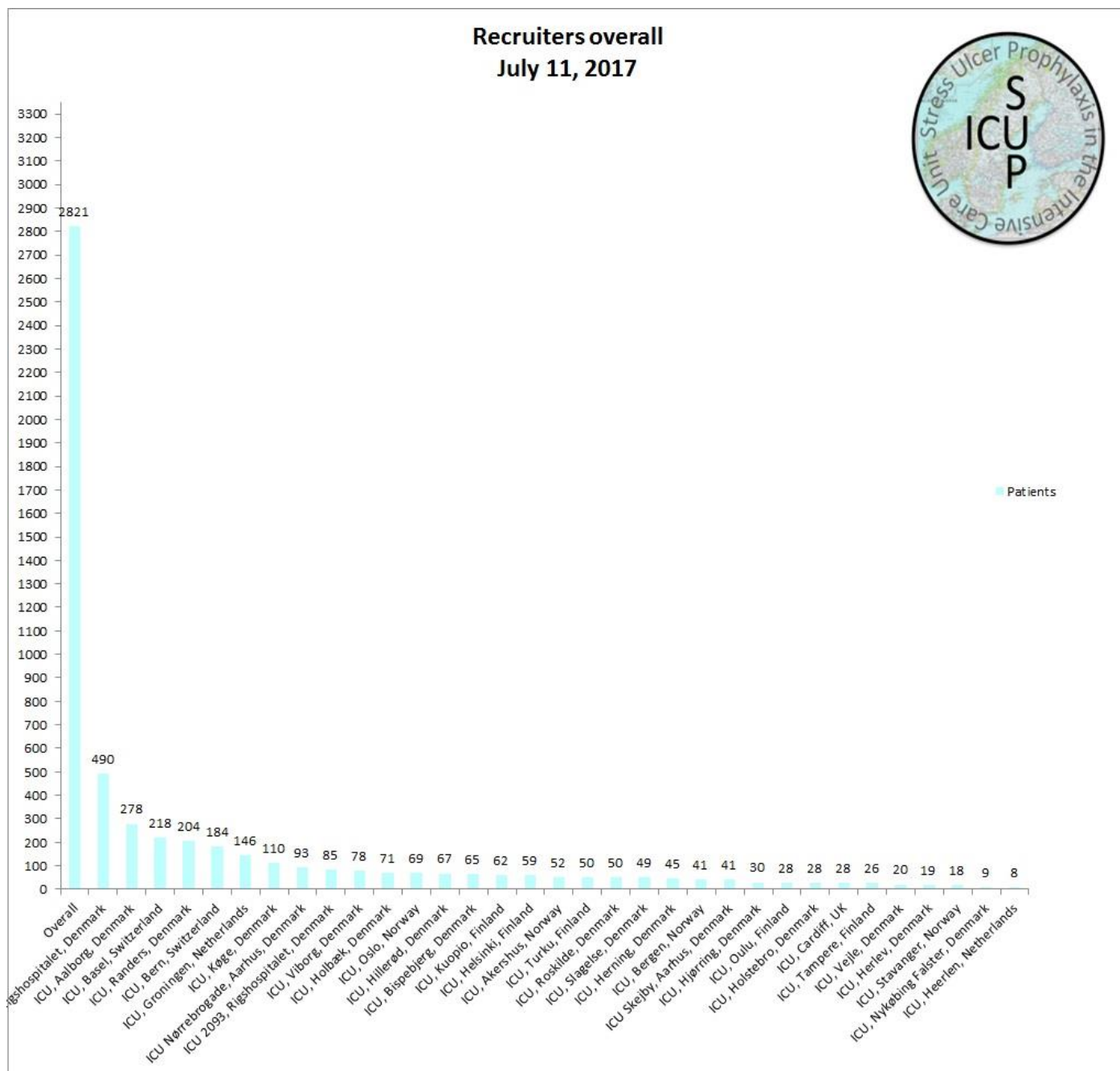




# Place in Site Master File #13

## SUP-ICU newsletter – July 2017



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



## Status

**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.**

Since the previous newsletter more than 119 patients have been randomised, and we have now randomised 2819 patients (84%). 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](http://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 June newsletter
- *Nykøbing Falster Hospital (DK)* and *Roskilde Hospital (DK)* are no longer active in the trial.

## Top recruiters

Top 5 overall recruiters in June were:

1. (Rigshospitalet 4131) (28)
2. Aalborg (18)
3. Rigshospitalet 2093 (16)
4. Aarhus Skejby (15)
5. Randers (11)

Congratulations to Aalborg for finishing as monthly top recruiter in June!

Rigshospitalet 2093 (Neuro ICU), Randers and Aarhus Skejby continue to randomise patients at a steady state.

## Important information

- **A previously mentioned trial medication will expire end of november 2017, why we need to randomise the last patient before September 1<sup>st</sup> 2017 to ensure the possibility 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 on the website (<http://www.cric.nu/sup-icu-annual-safety-report/>) – please archive this in your Site Master File section 4.
- *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 16% to go!

## SUP-ICU hotline

If you have any questions please send us an email ([soeren.marker.jensen.01@regionh.dk](mailto: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.

CRIC • Blegdamsvej 9, 7812 • 2100 Copenhagen Ø • +45 35 45 71 67 • [contact@cric.nu](mailto:contact@cric.nu) • [www.cric.nu](http://www.cric.nu)



Please archive this newsletter in your Site Master File.

**Best regards**

**Søren, Anders, Carl and Morten**