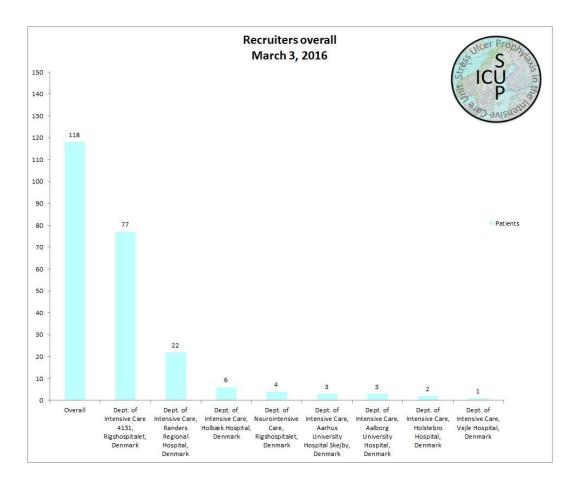


Place in Site Master File #13

SUP-ICU newsletter – March 2016

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



Status

We have now randomised 118 patients and eight sites are active. More sites are expected to start inclusion within the next couple of weeks. Finland, The Netherlands, Switzerland and Norway are expected to start inclusion of patients in April.

You can follow the inclusion at <u>www.sup-icu.com</u> (Press F5 to refresh the page and get the updated status).

Momentum

In order to be able to randomise 3350 patients in two years, it is important that all eligible patients are assessed for inclusion (screened) in the eCRF. Furthermore, this will ensure collection of high-quality data.

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Randers Hospital (a Danish 8 bed ICU) has managed to successfully randomise 22 patients in less than a month (1 in 4 patients admitted to the ICU have been randomised) by systematically assessing all patients admitted to the ICU. Concordantly, 1 in 3 patients admitted to the general ICU in Rigshospitalet, Denmark have been randomised.

Please contact us if you need input on how to systematically screen eligible patients.

Data entry and eCRF

Experiences with the eCRF so far are great. Data entry is easy and not very time-consuming (estimated time usage: baseline form 5-10 min and day forms 2-5 min).

Please remember to fill in the "discharge form", when patients are discharged from the ICU. This is especially important when patients are transferred to another ICU participating in the SUP-ICU trial, as continued administration of medicine (and data entry) is only possible following adequate discharge in the eCRF. Please call us if you need guidance on this issue.

If you experience any problems with the eCRF, including the medication dispensing system, please do not hesitate to contact the SUP-ICU hotline.

SUP-ICU hotline

If you have any questions please send us an email (<u>mette.krag.01@regionh.dk</u>) 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, Mette and Morten

