

CLASSIC newsletter - May 2019

Dear Friends – THANK YOU for your commitment!

Status

Since trial start **131 patients** have been randomised from 9 sites. Mean recruitment per week is 6 patients, and recruitment rates are generally increasing.



Sweden has joined the trial with ICUs at Huddinge and Södersjukhuset.

Norway is just about to start with ICUs at Rikshospitalet and Hamar as the first trial sites.

Future active sites

ICUs at Kolding and Aalborg (Denmark), Bern (Switzerland) and Pilsen (Czech Republic) are expected to start in May 2019.

Important information!

- All Note-to-file documents must be sent to Sponsor at classic@cric.nu, as we need to keep track of them.
- When 155 patients have completed 30-days enrollment, the first interim analysis will be conducted and fluid data will be evaluated by the Data Monitoring and Safety Committee.
 To ensure data quality for the interim analysis, please complete all dayforms for the patients included at your site.
- After the interim analysis, you will be invited to a CLASSIC meeting at Rigshospitalet (Copenhagen, Denmark) followed by a social dinner. We hope to see many investigators there! More information will follow.
- In case of a temporary breakdown of the eCRF, patients can still be randomised. Call the hotline at +45 3545 0606 and we will guide you.

Updates on the website

All changes to the CLASSIC Site Master File are documented in the LOG for site master file, available online at http://www.cric.nu/classic-log/. Make sure to print new documents and archive in your Site Master File accordingly.

Meet the CLASSIC investigators

ICU Viborg (Denmark) is overall top-recruiter in CLASSIC. The ICU has 10 mixed beds.

Christoffer Sølling, Senior specialist, PhD, is the responsible investigator at Viborg. Christoffer and Therese Straarup, MD, are coordinating screening and data entry of all CLASSIC patients at Viborg, where impressing 20 patients have been randomised in 2.5 months.

Christoffer and Therese describe: "We aim to keep a high quality of patient care and being a part of a large and relevant study as Classic is a way to keep up a culture in the department with focus on professional care following up-to-date evidence based treatments. We think the CLASSIC trial will create greater awareness of fluid administration in general in our ICU."



Christoffer Sølling, Senior specialist, MD PhD and Therese Straarup, MD from ICU Viborg (Denmark)

CLASSIC hotline

If you have any questions please send us an email (classic@cric.nu) or contact the CLASSIC hotline 24/7 (+45 3545 0606). 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.

Kind regards

The CLASSIC team

Tine, Morten, Peter, Andreas, Carl and Anders

