

CLASSIC newsletter – March 2020

Dear friends – we’re almost halfway!

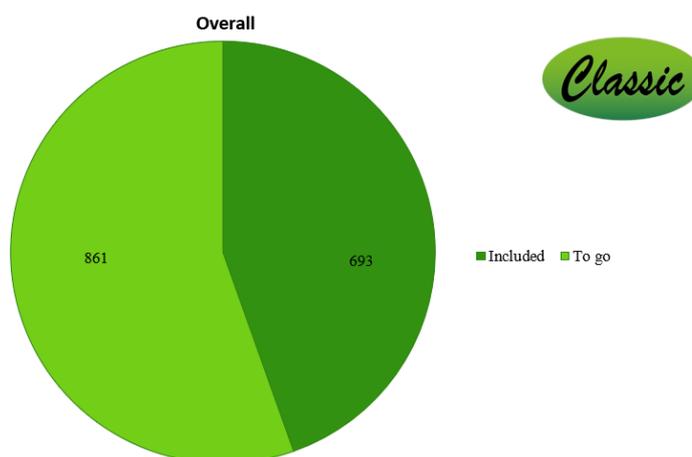
Status

Since trial start **693 patients** have been randomised by **24 sites in 7 countries**.

ICUs Basel (Switzerland) and Sundsvall (Sweden) have joined the trial.

We had an initiation visit with Intensive Care National Audit and Research Centre (ICNARC) and site investigators in the UK, and we look forward to welcoming the British sites in CLASSIC, which will be in good hands in the organisational framework of ICNARC.

When 777 patients have completed 90 days follow-up, the 3rd and last interim analysis will be conducted by the Data Monitoring and Safety Committee.



ICUs in the pipeline

-  Vall d’Hebron (Spain)
-  Helsinki, Tampere and Kuopio (Finland)
-  Saint Göran (Sweden)
-  Approximately 10 ICUs UK
-  Brno and Hradec Kralove (Czech Republic)

Top recruiters, February 2020

Monthly top-recruiters outside Sponsors center were **Hillerød** (Denmark) and **Rikshospitalet** (Norway). Congratulations!



Important information!

COVID-19

Patients tested positive for Coronavirus 2019 (COVID-19) may be included in CLASSIC.

We have added a question in the baseline and discharge forms to know if patients are positive for Coronavirus.

Whenever clinical workload allows for it, we hope you will also include these patients, as it will increase knowledge of fluid therapy in this subgroup.

Tips to minimize protocol violations in CLASSIC

- Are fluids indicated?
- Can sedation be minimized?
- Can other vasodilators be minimized?
- Reduce epidural?
- Lower respiratory pressures?
- Can the fluid be given orally instead?
- ... Call the hotline! (+45 3545 0606)

Consent forms in the eCRF

A consent form module is now available in the CLASSIC eCRF. It is being tested at Sponsors site throughout March and will be implemented at all Danish ICUs hereafter.

For international sites, the form will only be used if local law allows for upload of consents. You will be informed about it by your national investigator.

Screening

Only patients who fulfill **all** inclusion criteria are required to be screened.

Meet the CLASSIC investigators

The ICU at Bern University Hospital is one of the best recruiting sites in CLASSIC. Bern has an interdisciplinary 37-bed ICU with additional 16 intermediate care beds. National investigator for Switzerland is Prof. Stephan Jakob, with sub-investigator Dr. Carmen Pfortmüller.

“We have strong foot-hold in both experimental (large animal and experimental lab) and clinical research (single-center and large multi-national trials). Eight certified research nurses constitute the heart of our research unit and take care of study participants and data collection 365 days of the year. Our sophisticated electronic patient management system allows for real-time automatic data collection, and retrieval of data for clinical research. Fluid research is one of the focus areas of our department; hence, we are honored to participate in CLASSIC.” - Carmen Pfortmüller.



Study Team from left to right:

Laureta Fazlija, Research Nurse Assistant; Dr. Carmen Pfortmüller, Principal Investigator; Marianne Roth, Head Research Nurse; Rachele Mader, Research Nurse; David Zacharias, Study Coordinator

Contact

You can reach us at classic@cric.nu or +45 3545 0606 (available 24/7). If no one answers the phone, please leave a message with your phone number.

Please archive this newsletter in your Site Master File.

**Until next time,
Morten, Maj-Brit, Lene, Peter, Anders & Tine**

