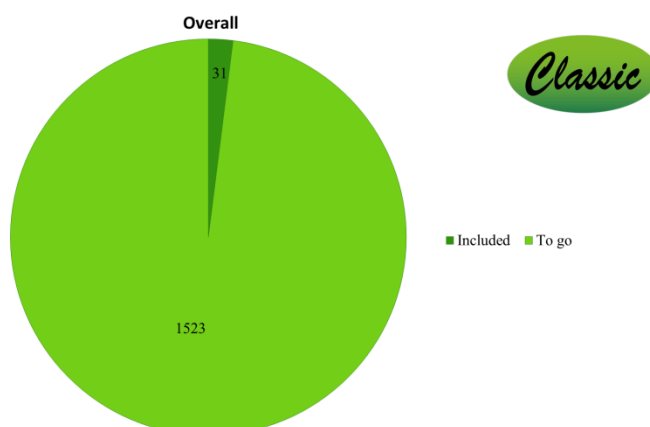




Place in Site Master File #13

CLASSIC newsletter – February 2019

Dear friends - **THANK YOU** for your commitment!

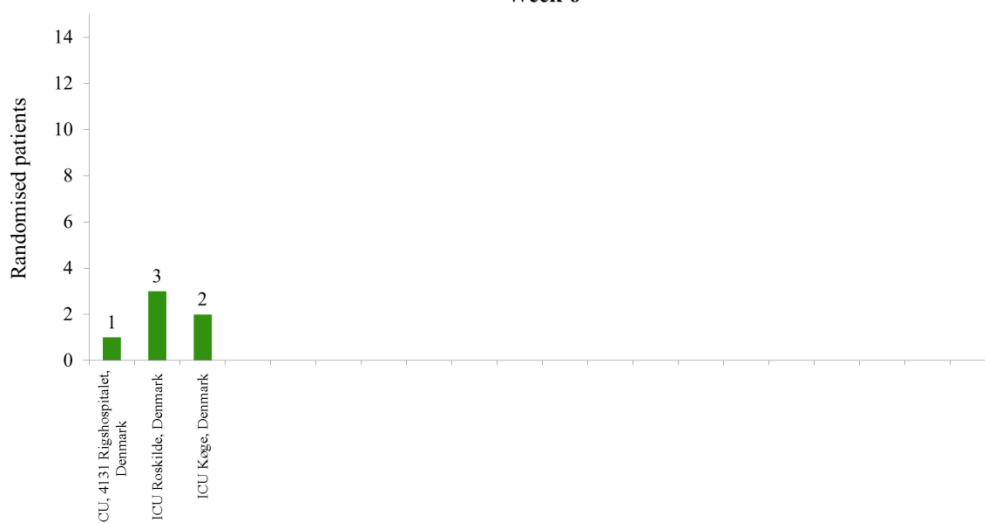


Status

Since the trial began on November 27th, 2018 at Rigshospitalet, 31 patients have been randomised. The ICUs at Roskilde, Køge, Viborg and Randers (all in DEN) have joined the trial. Now 5 sites are actively recruiting. A warm welcome!

Week 6 was the best week of the CLASSIC trial so far with 6 patients randomised, 3 of them at the ICU at Roskilde (DEN) who was the weekly top recruiter. Congratulations!

Top recruiters
Week 6



Future active sites

Sweden (3 sites), Norway (5 sites) will be the first international sites to join CLASSIC. Next Danish sites are the ICUs at Bispebjerg, Herning and Aalborg. Good progress with the paper work is being made in several other countries (e.g. Italy, Spain, Switzerland, Czech Republic and the United Kingdom).

Important information

At the Danish Intensivists Meeting, Hindsgavl (DEN), the CLASSIC group in Denmark got together. Some FAQ's were discussed. Here is an update:

Is parenteral nutrition allowed in the restrictive group?

→ **Yes**, $\geq 10\%$ glucose and parenteral nutrition solutions are allowed. Enteral nutrition should be initiated as soon as possible.

Can a patient who has been in the ICU for a long time and develops septic shock be included?

→ **Yes**, ICU admission time is not an exclusion criterion. A patient who has not before been included and develops a new septic event may be enrolled.

Does the exclusion criterion 'septic shock for more than 12 hours' include both vasopressors and p-lactate ≥ 2 ?

→ **No**, vasopressors for more than 12 hours is the exclusion criterion.

Does the inclusion criterion '1 L IV fluid 24 hours prior to screening' include all IV fluids?

→ **Yes**, it includes all IV fluids including IV fluids with medication and parenteral nutrition.

1-year follow-up

All participating ICUs are responsible of conducting 90-days and 1-year follow-up. The 1-year follow-up will assess health-related quality of life by EQ-5D-5L and EQ-VAS questionnaires and cognitive function by MoCa-MINI. The questionnaires should be filled-in by telephone interview and the patient's answers should be registered on specific paper forms (source data), which should be signed and archived at each trial site. The eCRF should be filled-in using data from the paper forms. A copy of the paper forms must be sent to the coordinating centre at the ICU at Rigshospitalet, Denmark. Further details about the 1-year follow-up will come.

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

The national investigator of Sweden, Maria Cronhjort, MD, PhD, is working as an intensivist at the ICU at Södersjukhuset in Stockholm, where she is the head of the research department.

Maria obtained approval for CLASSIC in Sweden. Since CLASSIC is a drug trial, consent from patients prior to enrollment is a demand by Swedish law. The team in Sweden will therefore enroll patients in CLASSIC early (e.g. from the emergency department with planned ICU admission). Maria hopes CLASSIC will set an example for Sweden to get approvals for deferred consent in critical care drug trials in the future. Maria and her team will conduct three sub-studies of CLASSIC about the effect of restrictive fluid management on glycocalyx degradation, inflammation and cardiac function. Protocols will soon be available. If your ICU is interested in participating, Maria Cronhjort can be contacted at:

maria.cronhjort@sl.se



Maria celebrated her 50th birthday on the day of CLASSIC initiation in Sweden

CLASSIC group

We have a new team member. Carl Steensen will be a part of the coordinating group at Rigshospitalet (DEN). He is a medical student doing a research year the ICU at Rigshospitalet. Warm welcome!

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

