

# **CLASSIC** newsletter - August 2019

## Dear Friends – THANK YOU for supporting the trial!

#### **Status**

Since trial start **300 patients** have been randomised from 17 sites in 4 countries. Mean recruitment per week has increased to 8 patients.



ICU in Pilsen (Czech Republic) is ready to randomise their first patient!



ICU Vall d'Hebron in Barcelona (Spain) will join the trial this fall



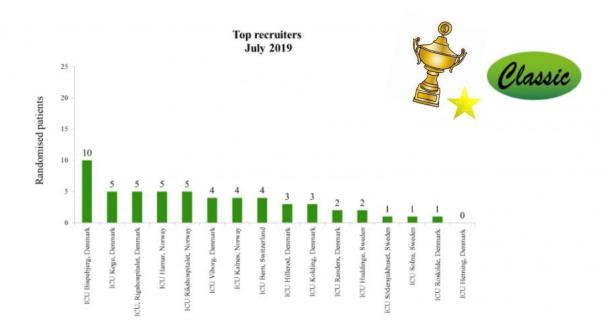
ICUs in and around Milan (Italy) will also join the trial in fall

## **Top-recruiters**

One ICU was unbeatable as top-recruiter this summer. Big congratulations to the team at Bispebjerg Hospital (Denmark) who randomised 10 patients in July!

Responsible CLASSIC investigators are Søren Hoffmann and Anders Bastiansen with great

support by research nurses and medical students responsible for consent and data entry.





The anesthesia and intensive care research team at Bispebjerg hospital (Denmark) in front of their new research facilities

## Important information!

- A protocol update (version 2.3) is now approved by Danish regulatory authorities.
   Protocol version 2.3 is now the valid version.
   Please print the protocol and approvals (attached in the e-mail with this newsletter and also available at <a href="https://www.cric.nu/CLASSIC">www.cric.nu/CLASSIC</a> ) and archive in your Site Master File #1 and #4
- The report form for adverse events in CLASSIC has been updated according to protocol
   2.3. Please also print this form and archive in Site Master File #14
- All coordinating site-investigators are invited to a social at the ESICM conference in Berlin.
   The dinner will take place on Tuesday October 1<sup>st</sup> at 19.00 pm. Let us know at <a href="mailto:classic@cric.nu">classic@cric.nu</a> if you will join us. Hope to see you there!

#### News

 The CLASSIC protocol and statistical analysis plan has been published: Meyhoff et al, Acta Anaesthesiol 2019, Conservative vs liberal fluid therapy in septic shock (CLASSIC) trial-Protocol and statistical analysis plan, PMID: 31276193, DOI: 10.1111/aas.13434

#### Meet the CLASSIC investigators

The national investigator of Czech Republic, Marek Nalos, MD PhD, is head of the medical ICU in the city of Pilsen. He recently returned after working 16 years as an intensivist in Sydney,

Australia, and he is bringing plenty experience from conducting large clinical trials with him. Marek and Lenka Pfauserova have been working hard for approvals of CLASSIC in Czech Republic, and now several ICUs from Pilsen, Prague and Brno are looking into joining the trial.

When the first patient is randomised into CLASSIC, it will be the first time Czech Republic participates in a CRIC trial!



Food and pilsner enjoyed in Pilsen with the Czech team

#### Contact

You can always reach us at <a href="mailto:classic@cric.nu">classic@cric.nu</a> or +45 3545 0606 (hotline available 24/7). If no one answers the phone, please leave a message with 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, Nick, Andreas, Carl, Peter, Morten and Anders

