

CLASSIC newsletter

Dear friends – thanks for supporting the trial!

Status

Since trial start **526 patients** have been randomised by 21 sites in 7 countries. Mean recruitment per week has increased to 10 patients.

Since the last newsletter we have celebrated that the ICU in Brussels randomised their first patient in CLASSIC. This is the first time Belgium is joining a CRIC trial!

We have also celebrated the 1-year birthday of CLASSIC (the first patient was randomised on

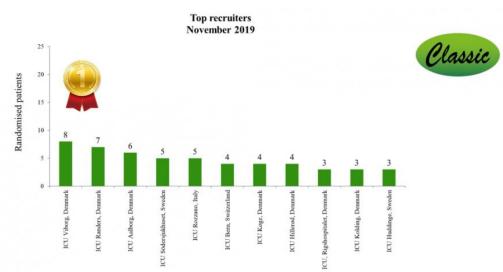
November 27th 2018), and that more than 1/3 of the trial size has been reached!

Future active sites

- W	ICU Vall d'Hebron in Barcelona (Spain)
+	ICUs Helsinki, Tampere, Kuopio and Lappeenranta (Finland)
+	ICU Basel (Switzerland)
-	ICU Sundsvall and medical ICU in Södersjukhuset (Sweden)
	Approximately 10 ICUs in the United Kingdom

Top recruiters

Monthly top-recruiter in November 2019 was ICU Viborg (Denmark) followed by ICU Randers (Denmark). Congratulations!



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Important information

Interim analyses

The dataset for the second interim analysis (30% of patients) has been sent to the DMSC. Thanks for your efforts with the data entry!

1-year follow-up

The follow-up of Danish patients has begun. The 1-year follow-up protocol is published (PMID: 31828753) Every ICU must certify one investigator, who is blinded to treatment allocation, to perform the 1year follow-up. Information to international sites will be sent out in the beginning of 2020.

Social

The annual investigator meeting for Danish investigators will take place at Hindsgavl on January 24th 2020. If you want something addressed at the meeting, don't hesitate to let us know at: <u>classic@cric.nu</u>. Hope to see you there!

Meet the CLASSIC investigators

The CLASSIC investigator of the month is one of the founding fathers! Peter Hjortrup initiated the CLASSIC trial program with Anders Perner in 2014 and was the coordinating investigator of the CLASSIC feasibility RCT, where a protocol restricting resuscitation fluid successfully reduced volumes of resuscitation fluid compared with standard care (PMID: 27686349). Further, he published important post-hoc analyses of the CLASSIC feasibility trial, investigating both hemodynamic parameters during fluid restriction (PMID: 28150304), and indications for fluid administration (PMID: 30318584). Peter Hjortrup is now in specialty training and is a driving force in the CLASSIC Steering Committee.



Peter Hjortrup, MD, PhD, intensivist in training



CLASSIC hotline

You can reach us at <u>classic@cric.nu</u> or +45 3545 0606 (available 24/7). If no one answers the phone, please leave a message with your phone number (as you are likely calling from a hidden number) and we will call you back ASAP.

Please archive this newsletter in your Site Master File.

...Last but not least

We are humbled by the support CLASSIC received in 2019!

In 2019, we have initiated 11 Danish ICUs and 6 countries – Sweden, Norway, Switzerland, Czech Republic, Italy and Belgium. Obtaining legal approvals to run trials and keeping the methodology to high standards may never have been more challenging than these days. It would never be possible without your support! Obtaining approvals, randomising patients, entering data, monitoring according to GCP, informing patients and relatives - you are all working to improve knowledge and outcomes of septic shock. A warm thank you! We are looking forward to continuing the work in 2020.

A Merry Christmas and Happy New Year!

Morten, Maj-Brit, Peter, Tine & Anders



