

CLASSIC newsletter – February 2020

Dear friends – thanks for your support in 2019 – looking forward to a great 2020!

Status

Since trial start 607 patients have been randomised by 21 sites in 7 countries.

Since the last newsletter we have conducted the 2nd interim analysis, and the trial reached a new record for highest weekly inclusion rate (21 patients).

At the time of writing, 71% of the patients have been included from Danish ICUs. Anyone who wants to challenge the Danes?

ICUs in the pipeline

| (M) | ICLL Vall d'Hebren in Barcelona | (Snain) |
|-----|---------------------------------|---------|
| | ICU Vall d'Hebron in Barcelona | (Spain) |

ICUs Helsinki, Tampere, Kuopio and Lappeenranta (Finland)

ICU Basel (Switzerland)

ICU Sundsvall and Saint Göran (Sweden)

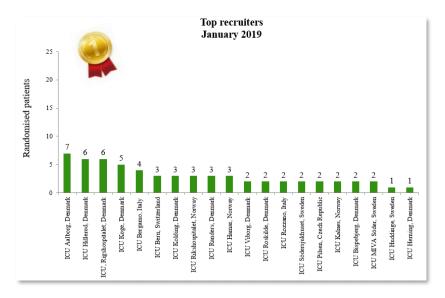
Approximately 10 ICUs in the United Kingdom

ICU Brno and Hradec Kralove (Czech Republic)

Top recruiters

Monthly top-recruiter in January 2020 was ICU Aalborg (Denmark) followed by ICU Hillerød

(Denmark). Congratulations!



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Important information

Interim analyses

Data from the second interim analysis (466 patients with 30-day follow-up) show that the patients received a median of 3000ml IV fluids in the last 24hrs prior to inclusion, their highest lactate value at baseline was median 3.8mmol/L, and the highest infusion rate of noradrenaline at baseline was median 0.22µg/kg/min.

In total, 25% of patients in the IV fluid restrictive group had one or more protocol violations during ICU stay versus 17% in the standard-care group.

Aims for 2020:

- increase inclusion rates



decrease protocol violations

How to minimize protocol violations?

Acknowledging that ICU patients are different, and receive several treatments parallel with IV fluids, we recommend considering the following *before* IV fluids violating the protocol are given:

- 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)

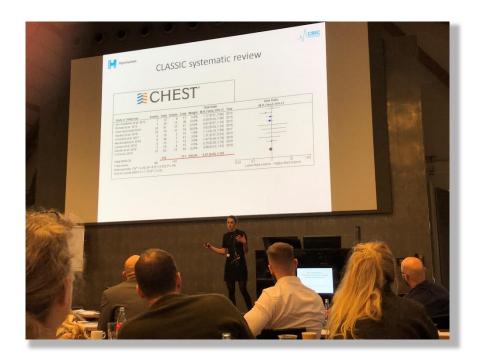
If active therapy has been withdrawn in a patient, please fill out the withdrawal form in the eCRF. This may also minimize violations.

Meet the CLASSIC investigators...

...Will return next newsletter!

Instead you will get a photo from the Danish Society of Intensive Care Medicines annual meeting, where coordinating investigator, Tine Meyhoff, presented the CLASSIC trial program.

A systematic review of RCTs investigating higher versus lower fluid volumes in adults with sepsis has just been published in CHEST. It can be accessed by <u>PMID: 31982391</u>. (Spoiler alert: very low quantity and quality of evidence supporting the decision on IV fluid volume).



CLASSIC hotline

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 (you are likely calling from a hidden number) and we will call you back ASAP.

Spread around the newsletter, and please archive in your Site Master File.

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



