GODIF

GODIF Newsletter March 2021 to May 2021

Thank you for committing to the GODIF trial!

Dear friends and colleagues,

We hope you all are doing well and that the COVID 19 pandemic is loosening the grip on your departments and everything is slowly returning to normal.

The waiting time is over. We happy to inform you that we have finally received approval of the minor changes to our protocol and we will very soon be up and running again after a 3 months break. We would like to invite you to an online team meeting where we present the changes on the 26th of May from 15:15 to 16:15. Thereafter all sites will be open for randomisations again.

All the relevant documents will be revised and ready to download from the homepage (www.cric.nu/godif/).

We will here present an overview of the changes for the protocol version 2.6:

The definition fluid overload and neutral fluid balance is changed. Instead of looking strictly at the cumulative fluid balance on the fluid charts, fluid overload is now assessed by the treating clinician according to the following four parameters: cumulative fluid balance, daily fluid balance, changes in body weight and clinical examination (e.g. oedema, congestion on chest X-ray e.c.t.). Patients can be included if the fluid accumulation is fulfilling the minimum criteria in the table below and the other inclusion criteria (adult, acute admission, clinical stable).

Height	Men	Women
≤159 cm	+3000 ml	+2500 ml
160 – 169 cm	+3500 ml	+3000 ml
170 – 179 cm	+4000 ml	+3500 ml
180 – 189 cm	+4500 ml	+4000 ml
≥190 cm	+5000 ml	+4500 ml

The estimation of fluid accumulation must be documented in the inclusion note.
The minimum daily negative fluid balance is no longer calculated but can be found in the following table:

Height	Men	Women
≤159 cm	-1300 ml	-1200 ml
160 – 169 cm	-1500 ml	-1400 ml
170 – 179 cm	-1700 ml	-1600 ml
180 – 189 cm	-1900 ml	-1800 ml

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≥190 cm	-2000 ml	-1900 ml

In the dayforms we will from now on register the daily fluid balance instead of the cumulative fluid balance.

When the clinical team around the patient assess that neutral fluid balance is reached according to the four parameters it must be documented in the patient file, and trial drug can be paused. If the patient later accumulate fluid, assessed by the treating clinicians, trial drug must be restarted.

The possibility to adjust the cumulative fluid balance is removed. The feature is no longer relevant, since the goal of the treatment now is based on an assessment of four parameters and not the cumulative fluid balance alone.

The resuscitation algorithm is simplified. If a patient becomes hemodynamic unstable during the trial with MAP<50 mmHg or lactate > 4.0 mmol/l or mottling beyond the kneecaps, the trial drug must be paused and resuscitation with crystalloid be performed. When the patient is without any of the three parameters for hypoperfusion and assessed stable enough to tolerate fluid removal by the clinical team, the trial drug can be restarted at a dose at the treating physician's discretion. Please make a note about this in the file.

As a new thing we will register sodium, potassium and chloride daily.

We hope that these changes will make it easier to include the right patients and to adhere to the protocol. Because the definition of fluid overload and neutral fluid balance has changed the study population might be slightly different from before, we have decided to include 1000 new patients on this protocol. A feasibility study will be made of the first 41 patients.

We are looking forward to seeing you online. If some of you cannot make it to the meeting please let me know so we can arrange another meeting.

All the best,

Morten and Sine

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Kind Regards form the GODIF team
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We look very much forward to further collaboration. Thank you for your support!