GODIF

Goal directed fluid removal with furosemide in intensive care patients with fluid overload

GODIF trial synopsis

Title	Goal directed fluid removal with furosemide in intensive care patients with fluid overload – A randomised, blinded, placebo-controlled trial (GODIF)
Short title	The GODIF trial
Objectives	To assess the benefits and harms of fluid removal with furosemide vs placebo on patient-important outcome measures in adult ICU patients with fluid overload.
Population	Adult ICU patients with fluid overload of 5 % or more according to ideal body weight
Interventions	Furosemide infusion to achieve and maintain a neutral cumulative fluid balance.
Comparator	Placebo (saline 0.9%)
Outcomes	**Primary**: Days alive and out of hospital at day 90 after randomisation **Secondary**: 1. All-cause mortality at day 90 after randomisation 2. Days alive at day 90 without life support (vasopressor/inotropic support, invasive mechanical ventilation, or renal replacement therapy) 3. All-cause mortality at 1 year after randomisation 4. Number of participants with one or more serious adverse events (SAEs) and serious adverse reactions (SARs) to furosemide 5. Health-related quality of life according to EuroQoL (EQ)-5D-5L at 1 year 6. EQ-VAS score at 1 year 7. Participants' subjective assessment of their quality of life since the treatment in the ICU (unacceptable/neutral/acceptable) at 1 year 8. Cognitive function 1 year after randomisation as assessed by the Montreal Cognitive Assessment (MoCA 5 min/telephone) score
Eligibility	**Inclusion criteria:** 1. Acute admission to the ICU **AND** 2. Age ≥ 18 years of age **AND** 3. Fluid accumulation ≥ 5% of ideal body weight *estimated* according to the daily fluid charts, the cumulative fluid balance, development in body weight, and clinical examination **AND** 4. Clinical stability assessed by clinicians (minimum criteria: MAP > 50 mmHg and maximum infusion of 0.20 microgram/kg/minute of noradrenaline and lactate < 4.0 mmol/L) **Exclusion criteria:** 1. Known allergy to furosemide or sulphonamides 2. Known pre-hospitalization advanced chronic kidney disease (eGFR < 30 mL/minute/1.73 m^2 or chronic RRT) 3. Ongoing RRT 4. Anuria for ≥ 6 hours 5. Rhabdomyolysis with an indication for forced diuresis 6. Ongoing life-threatening bleeding 7. Acute burn injury of more than 10 % of the body surface 8. Severe dysnatremia (p-Na < 120 or > 155 mmol/l) 9. Severe hepatic failure as per the clinical team 10. Patients undergoing forced treatment 11. Pregnant women 12. Informed consent not obtainable
Sample size	2 x 500 an overall improvement of 8% of the primary outcome (two sided α=0.05 and β=0.1)
Trial duration	The trial intervention will continue for a maximum of 90 days. Follow-up at day 90 and 1-year post randomisation. This version of the trial was initiated June 2021.

Anæstesiologisk afdeling Nordsjællands hospital ● Dyrehavevej 29 ● 3400 Hillerød
+45 4829 6773 ● godif@cric.nu ● www.cric.nu/godif/