|  |  |
| --- | --- |
| **Protocol title** | **GODIF**Goal directed fluid removal with furosemide in intensive care patients with fluid overload – A randomised, blinded, placebo-controlled trial (GODIF)EudraCT: 2019-004292-40; ClinicalTrials.gov: NCT04180397 |
| **SOP name** | Procedure for escape medicine and escape renal replacement therapy |
| **Version** | 1.0 |
| **Applied from** | 02.06 2020 |

|  |
| --- |
| **Target population**: Site investigators and research staff |
| **Responsible party**: Sponsor, Senior staff specialist and Associate Professor Morten Bestle |
| **Created by**: Coordinating Investigator; Sine Wichmann |
| **Objective*** To define criteria for escape open label furosemide
* To define criteria for escape renal replacement therapy
* To ensure uniform usage and registration of escape procedures
 |
| **Description:**Open label furosemide must only be used in case of:* Hyperkalaemia (p-K > 6.0 mmol/L
* Respiratory failure (P/F-ratio < 26 kPa (200 mmHg)) and pulmonary oedema and treating physician has a suspicion of respiratory deterioration is due to fluid overload.

Escape doses must be described in the medical record. The maximum dose of furosemide per 24 hours is 1500 mg and must not be exceed. The infusion of trial drug must continue in case of indication of escape open label furosemide. On maximum trial drug infusion, the patient might get 960 mg furosemide in 24 hours.Renal replacement therapy must only be started when severe complications in fluid, electrolyte, and acid-base balance occur:* Hyperkalaemia (p-K > 6.0 mmol/L
* Respiratory failure (P/F-ratio < 26 kPa (200 mmHg)) and pulmonary oedema and treating physician has a suspicion of respiratory deterioration is due to fluid overload.
* Severe metabolic acidosis attributable to acute kidney injury (pH < 7.20 and SBE < -10 mmol/L)
* Persistent acute kidney injury > 72 hours (defined as: oliguria/anuria or S-creatinine has not declined to 50% from peak value).

When escape renal replacement therapy is initiated the trial drug must be paused as long the patient receives dialysis. Trial drug must be re-started when renal replacement therapy is paused or stopped. Use of escape renal replacement therapy must be described in the medical record. |
| **Responsible party for administration and registration of Escape Protocol:**Site investigators and research staff. |
| **Approved 02.06 2020**: Sponsor, Morten Bestle |