**Plan for data verification**

**Goal directed fluid removal with furosemide in intensive care patients with fluid overload – A randomised, blinded, placebo-controlled trial (GODIF).**

**EudraCT-nr. 2019-004292-40**

**Level I:** systematic data verification of all data in the case report form. Applies to the first 3 trial participants and hereafter until a total of 10% of participants for each trial site has been monitored.

**Level II:** Selected data on all trial participants, who has not been selected for ‘Level I’.

| **Data** | **CRF****Code** | **I** | **II** | **Comments** |
| --- | --- | --- | --- | --- |
| **CONSENT FORM** |  |  |  |  |
| **Informed consent** | C1a-C6 | X | X | According to national regulations  |
|  |  |  |  |  |
| **Consent stated in medical record**  |  | X | X | According to national regulations  |
| **SCREENING** |  |  |  |  |
| **Inclusion criteria****Estimated fluid accumulation, height and weight** | S2-S4FL1-FL3 | XX | XX | The estimated fluid accumulation must be stated in the medical record. Often it will be stated in the inclusion note. |
|  |  |  |  |  |
| **Exclusion criteria** | S5-S17 | X | X |  |
|  |  |  |  |  |
| **Patient****Acute kidney injury****SMS-ICU score** | A1, A1a, A2, A3SS1-SS5 | XX |  | If A1 is ‘measured’ then the value can be checked in the medical record. If it is ‘calculated’ the value cannot be checked. |
| **BASELINE** |  |  |  |  |
| **Baseline** | BL1-BL15 | X |  |  |
| **DAY FORM** |  |  |  |  |
| **Fluids and trial drug**  | D1-D5 | X |  |   |
|  |  |  |  |  |
| **Blood samples** | B1-B4 | X |  |  |
|  |  |  |  |  |
| **Major protocol violation on this day** | MPV1-MPV3 | X |  |  |
|  |  |  |  |  |
| **Co-interventions** | D6-D10 | X |  |  |
|  |  |  |  |  |
| **Serious Adverse Events (SAEs)** | SAE1-SAE6 | X |  | Systematic data verification will be performed if a SAE is ’yes’ and at Sponsors site it will be controlled that a ‘Note to file’ is archived in Trial Master File #13 or a mail correspondence has taken place. This is for all day forms until day 90. |
|  |  |  |  |  |
| **Serious Adverse Reactions (SARs)** | SAR1-SAR10 | X | X | Systematic data verification will be performed if a SAE is ’yes’ and at Sponsors site it will be controlled that a ‘Note to file’ is archived in Trial Master File #13 or a mail correspondence has taken place. This is for all day forms until day 90. |
| **DISCHARGE AND READMISSION** |  |  |  |  |
| **Discharge and Readmission Form** | DC | X |  |  |
| **WITHDRAWAL** |  |  |  |  |
| **Withdrawal Form** | W1-W3b | X |  |  |
| **90 DAYS FOLLOW-UP** |  |  |  |  |
| **Follow-up day 90** | FU1-FU5 | X | X |  |