GODIF

Annual Safety report GODIF trial

EudraCT number	**2019-004292-40**
Clinical Trial Title	**Goal directed fluid removal with furosemide in intensive care patients with fluid overload – A randomised, blinded, placebo-controlled trial (GODIF).**
Sponsor	**Morten Bestle**
Designated reporter	**Sine Wichmann**
Danish Medicines Agency Journal Number	**2019121067**
Ethics Committees case number	**H-19080597**
Date of initial authorisation	**February 29, 2020**

Period of reporting: January 1, 2021 to December 31, 2021.

SAR in the period of reporting: 50 included patients. Number of SARs: 3
Number of patients with SARs: 2

SUSAR in the period of reporting: 50 included patients, 0 SUSAR.

Conclusions on observed SAR/SUSAR:
Number of patients with one or more of the following SARS:

2	Severe electrolyte disturbance (p-K < 2.5 mmol/L, p-Na < 120 mmol/L, p-Cl < 90 mmol/L)
0	Aplastic anaemia
0	Agranulocytosis
0	Pancreatitis
0	Circulatory collapse leading to cardiac arrest
0	Seizures because of furosemide induced low calcium or magnesium
0	Steven Johnsons syndrome
0	Toxic epidermal necrolysis
1	Hearing impairment/loss
0	Anaphylaxis

One participant experienced a plasma chloride of 87 mmol/l once on to separate days. The patient did not have any symptoms and no intervention was made. It was closely observed, and the low chloride was fast and spontaneous corrected. One participant (a multi-trauma patient) experienced light hearing impairment after wakening up from sedation. The patient was taken out of the trial immediately. The participant had only received 7 ml of trial drug.
The SARs to the trial drug (furosemide/placebo) are documented each day for all patients without the clinicians' decisions on a causal relationship between trial drug and SARs observed.

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Benefit-risk evaluation:
The reported cases did not give rise to any new safety concerns as all patients are closely monitored in the Intensive Care department. Risk and benefits for the patients are considered unchanged.

Implication for the clinical trial population:

Change in /amendment to protocol	☐ YES	☒ NO
Change in study procedures	☐ YES	☒ NO
Change in patient information	☐ YES	☒ NO
Change in informed consent form	☐ YES	☒ NO

Date: 5/1-2022 **Signature:**