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 29th 2020**

Period of reporting: August 17th, 2020 to December 31st, 2020.
(Initiation of trial: August 17th, 2020)

SAR in the period of reporting: 35 included patients. Number of SARs: 8
Number of patients with SARs: 3

SUSAR in the period of reporting: 35 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
1	Circulatory collapse leading to cardiac arrest
0	Seizures because of furosemide induced low calcium or magnesium
0	Steven Johnsons syndrome
0	Toxic epidermal necrolysis
0	Hearing impairment/loss
0	Anaphylaxis

One patient experienced shortly circulatory collapse leading to cardiac arrest in a situation with serous gastrointestinal bleeding. The patient was shortly stabilised with adequate treatment. The trial drug was paused but days later restarted with no further events.

SAR to trial drug (furosemide/placebo) are documented each day for all patients without 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: 24/1-2021 **Signature**:

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