



Annual Safety report CLASSIC trial

EudraCT number	2018-000404-42
Clinical Trial Title	The Conservative vs. Liberal Approach to fluid therapy of Septic Shock in Intensive Care (CLASSIC) trial
Sponsor	Anders Perner, Professor, PhD
Designated reporter	Tine Sylvest Meyhoff, MD, PhD-student
Medicines Agency journal number	2018020596
Ethics Committees case number	H-18006255
Date of initial authorization	March 20 th 2018

Period of reporting: April 2nd 2019 to March 10th 2020
(Initiation of trial: November 27th 2018)

SAR in the period of reporting: 602 included patients. Number of SARs: 55.
Number of patients with SARs: 27.

SUSAR in the period of reporting: 602 included patients, 0 SUSAR.

Conclusions on observed SAR/SUSAR:

Number of patients with one or more of the following SARs:

Tonic-clonic seizures:	5
Severe hyponatremia:	8
Severe hyperchloremic acidosis:	13
Anaphylactic reaction	1
Central pontine myelinolysis	0
Severe metabolic alkalosis	2

SAR to IV crystalloids are documented each day for all patients without clinicians decisions on a causal relationship between the IV fluids given administered and SARs observed.

Benefit-risk evaluation:

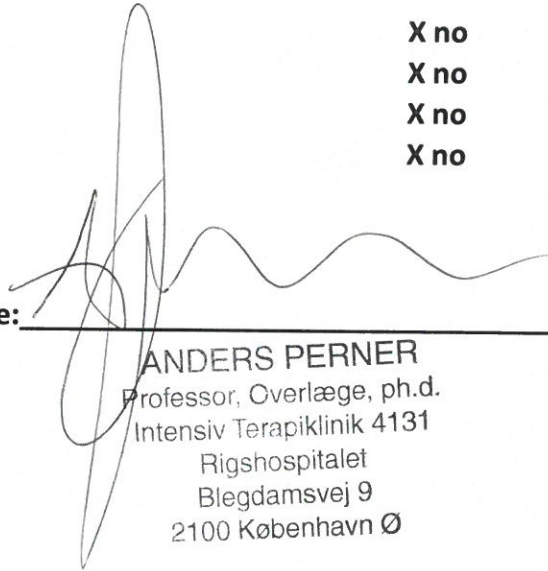
Based on the above reported, the risk and benefits for the patients are considered unchanged.

Implication for the clinical trial population:

- | | | |
|-----------------------------------|------------------------------|--|
| Change in / amendment to protocol | <input type="checkbox"/> yes | <input checked="" type="checkbox"/> no |
| Change in study procedures | <input type="checkbox"/> yes | <input checked="" type="checkbox"/> no |
| Change in patient information | <input type="checkbox"/> yes | <input checked="" type="checkbox"/> no |
| Change in informed consent form | <input type="checkbox"/> yes | <input checked="" type="checkbox"/> no |

Date: 30-03-2020

Signature: _____



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