



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, 2018

Period of reporting: March 10, 2020 to March 24, 2021
(Initiation of trial: November 27, 2018)

SAR in the period of reporting: 546 included patients. Number of SARs: 28.
Number of patients with SARs: 24.

SUSAR in the period of reporting: 546 included patients, 0 SUSAR.

Conclusions on observed SAR/SUSAR:

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

Tonic-clonic seizures:	4
Severe hyponatremia:	9
Severe hyperchloremic acidosis:	7
Anaphylactic reaction	3
Central pontine myelinolysis	0
Severe metabolic alkalosis	1

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 | X no |
| Change in study procedures | <input type="checkbox"/> yes | X no |
| Change in patient information | <input type="checkbox"/> yes | X no |
| Change in informed consent form | <input type="checkbox"/> yes | X no |

Date: March 24, 2021

Signature: _____

