



Final 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	Praleene Sivalan, MD, PhD-student 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: November 27, 2018 to February 14, 2022.

SAR in the period of reporting: 1554 included patients.

Number of SARs: 111

Number of patients with SARs: 63

SUSAR in the period of reporting: 1554 included patients. 0 SUSAR.

Conclusions on observed SAR/SUSAR:

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

Severe hyponatremia:	23
Severe hyperchloremic acidosis:	23
Tonic-clonic seizures:	14
Severe metabolic alkalosis	6
Anaphylactic reaction	4
Central pontine myelinolysis	0

SARs 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.

CRIC • Blegdamsvej 9, 7812 • 2100 Copenhagen Ø • +45 35 45 71 67 • contact@cric.nu • www.cric.nu



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: April 26, 2022

Signature: _____

