



Annual Safety report SUP-ICU Trial

EudraCT number	2015-000318-24
Clinical Trial Title	Stress Ulcer Prophylaxis in the Intensive Care Unit – SUP-ICU Trial
Sponsor	Morten Hylander Møller, MD, PhD
Designated reporter	Søren Marker, MD, PhD-student
Medicines Agency journal number	2015110369
Ethics Committees case number	H-16036585 (prev. case number: H-15003141)
Date of initial authorization	June 8, 2015

Period of reporting: June 2 2017 – January 22 2018 (end of trial 90-day follow-up period)

SAR in the period of reporting: 3350 included patients, 0 SAR.

SUSAR in the period of reporting: 3350 included patients, 0 SUSAR.

Conclusions on observed SAR/SUSAR:

None

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: 27.03.2018

Signature: 