



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 Jensen, MD, PhD-student
Medicines Agency journal number	2015110369
Ethics Committees case number	H-15003141
Date of initial authorization	June 8 th 2015

Period of reporting: January 4th to July 5th 2016
 (Initiation of trial awaited GCP-approval: January 1st 2016)

SAR in the period of reporting: 620 included patients, 0 SAR.
SUSAR in the period of reporting: 620 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: 7/7/16 Signature:

