

Annual Safety report, Data Monitoring and Safety Committee The HOT-ICU Trial

EudraCT number	2017-000632-34
Clinical Trial Title	Handling Oxygenation Targets in the Intensive Care Unit – HOT-ICU Trial
Sponsor	Bodil Steen Rasmussen, MD, PhD
Designated reporter	Olav Lilleholt Schjørring, MD, PhD student
Medicines Agency journal number	2017021858
Ethics Committees case number	N-20170015
Date of initial authorisation	June 14, 2017

Period of reporting: September 27, 2018 to June 19, 2019

SAR in the period of reporting: 851 included patients, 0 SAR

SUSAR in the period of reporting: 851 included patients, 0 SUSAR

SAEs in the period of reporting: 851 included patients

- 8 patients with new myocardial ischaemia
- 10 patients with new ischaemic stroke
- 19 patients with new intestinal ischaemia
- 288 patients with new episode of shock

Definitions of SAE:

New myocardial ischaemia: Onset of ST-elevation myocardial infarction, non-ST elevation myocardial infarction OR unstable angina pectoris according to the criteria in the clinical setting in question (e.g. elevated biomarkers, ischaemic signs on ECG and clinical presentation) AND receiving treatment as a consequence of this: reperfusion strategies (PCI/thrombolysis) or initiation/increased antithrombotic treatment

New ischaemic stroke: Verified new ischaemia on cerebral CT or MRI scan

New intestinal ischaemia: Onset of gastric, mesenteric OR colonic ischaemia, verified through exploratory or diagnostic abdominal surgery, gastroscopy or colonoscopy, or findings of intestinal ischaemia on CT- or MRI-angiography

New episode of shock: p-Lactate > 2 mmol/L AND use of vasopressor or inotropic treatment in any given day AND no shock at baseline or out-of-shock in any of the foregoing post-randomisation days

Date:

20/JUNE/2019

Signature:

