

**Annual Safety report AID-ICU trial**

EudraCT number	2017-003829-15
Clinical Trial Title	Agents Intervening against Delirium in the Intensive Care Unit – AID-ICU trial
Sponsor	Lone Musaeus Poulsen, MD
Designated reporter	Nina Christine Andersen-Ranberg, MD, PhD-student
Medicines Agency Journal number	2017-101527
Ethics Committee case number	SJ-646
Date of initial authorization	December 5, 2017

Period of reporting: January 1th 2020 to December 31 2020

SAR in the period of reporting: 382 included patients, 2 SARs

SUSAR in the period of reporting: 382 patients included, 0 SUSAR

Conclusions in observed SAR/SUSAR:

One case of Ventricular Tachycardia (VT) has been reported among trial participants in 2020. The patient that experienced VT were discontinued from trial medication and treated according to local guidelines. One case of extrapyramidal symptoms has been reported among trial participants in 2020. Trial medication was discontinued and symptoms resolved after a few days.

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: 5/1/21

Signature: 