

Protocol title	AID-ICU Agents Intervening against Delirium in the Intensive Care Unit EudraCT no: 2017-003829-15, ClinicalTrials.gov: NCT03392376
SOP name	Acute Hepatic Failure
Version	1.0
Replaces version	NA
Applies from	20 August 2019

Target population: Site investigators and Research staff			
Responsible party: Sponsor, MD, Chief physician Lone Musaeus Poulsen			
Created by: Coordinating Investigator; Nina Christine Andersen-Ranberg			
1. Objective			
<ul style="list-style-type: none"> To define Acute Hepatic Failure in the AID-ICU trial for the purpose of reporting Serious Adverse Reactions (SARs) to haloperidol To uniform registration of SAR in the AID-ICU trial 			
2. Description:			
2.1 Definition of Hepatic Failure:			
Hepatic failure is defined as Severe Hepatic failure (Child-Pugh Class C) or severe hepatic dysfunction presented by Billirubin concentration $\geq 50 \mu\text{mol/l}$ (3 mg/dl) AND Alanine Aminotransferase concentration (ALAT) $\geq 3 \times$ upper reference value.			
2.2 Definition of Acute Hepatic Failure:			
The hepatic failure is defined as acute when it develops within two weeks.			
2.3 Child-Pugh Score			
Factor	1 point	2 points	3 points
Billirubin	< 34 $\mu\text{mol/l}$ < 2 mg/dL	34-50 $\mu\text{mol/l}$ 2-3 mg/dL	> 50 $\mu\text{mol/l}$ > 3 mg/dL
Albumin	> 35 $\mu\text{mol/l}$ > 3.5 g/dL	28-35 $\mu\text{mol/l}$ 2.8-3.5 g/dL	< 28 $\mu\text{mol/l}$ < 2.8 g/dL
INR	< 1.7	1.7-2.3	>2.3
Ascites	None	Mild	Moderate to Severe
Hepatic Encephalopathy	None	Grade I-II (or suppressed with medication)	Grade III-IV (or refractory)
Class A Class B Class C			
Total points	5-6	7-9	10-15

2.4 If a trial participant experience an Acute Hepatic Failure according to the above definition, please click 'Yes' in SAR4 on the dayform(s). Reporting of SAR shall be done in accordance with instructions in trial documents on SAR/SUSAR achieved in 9aV in Site Master File.

Responsible party for evaluating Acute Hepatic Failure

Site investigators

Approved

Sponsor, Lone Musaeus Poulsen