



## Clinical trial results:

### Effect of norepinephrine infusion on hepatic blood flow during goal-directed hemodynamic therapy.

#### Summary

EudraCT number	2018-004139-66
Trial protocol	BE
Global end of trial date	23 October 2020

#### Results information

Result version number	v1 (current)
This version publication date	06 July 2024
First version publication date	06 July 2024
Summary attachment (see zip file)	Final Study Report (Finale_Study_Report.pdf)

#### Trial information

##### Trial identification

Sponsor protocol code	AGO/2018/006
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	UZ Gent
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	Hiruz CTU, Ghent University Hospital, +32 93320530, hiruz.ctu@uzgent.be
Scientific contact	Hiruz CTU, Ghent University Hospital, 093320530 93320530, hiruz.ctu@uzgent.be

Notes:

#### Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

## Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 August 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	23 October 2020
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

To assess the effect of norepinephrine infusion (NOR) on hepatic blood flow and hepatic vascular pressures during goal-directed hemodynamic therapy.

Protection of trial subjects:

See attachement

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 May 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 28
Worldwide total number of subjects	28
EEA total number of subjects	28

Notes:

### Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	10
From 65 to 84 years	18
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

See attachement

### Pre-assignment

Screening details:

See Attachement

### Period 1

Period 1 title	Overall Trial (overall period)
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Is this the baseline period?	Yes
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Allocation method	Non-randomised - controlled
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Blinding used	Not blinded
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Blinding implementation details:

Not relevant

### Arms

Are arms mutually exclusive?	Yes
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<b>Arm title</b>	Group S
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Arm description:

See attachement

Arm type	group S
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Investigational medicinal product name	Norepinephrine
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Solution for infusion
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Routes of administration	Infusion
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Dosage and administration details:

See attachement

<b>Arm title</b>	Group NS
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Arm description:

See attachement

Arm type	Group NS
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Investigational medicinal product name	Norepinephrine
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Solution for infusion
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Routes of administration	Infusion
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Dosage and administration details:

See attachement

<b>Number of subjects in period 1</b>	Group S	Group NS
Started	20	8
Completed	20	8

## Baseline characteristics

## End points

### End points reporting groups

Reporting group title	Group S
Reporting group description: See attachement	
Reporting group title	Group NS
Reporting group description: See attachement	

### Primary: Primary

End point title	Primary <sup>[1]</sup>
End point description:	
End point type	Primary
End point timeframe: See attachement	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: See attachement

End point values	Group S	Group NS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	8		
Units: Subjects	20	8		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Secondary

End point title	Secondary
End point description:	
End point type	Secondary
End point timeframe: See attachement	

<b>End point values</b>	Group S	Group NS		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	8		
Units: Subjects	20	8		

## Statistical analyses

No statistical analyses for this end point

## Adverse events

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

During the study

Assessment type	Non-systematic
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### Dictionary used

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Dictionary name	MedDRA
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Dictionary version	0
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Frequency threshold for reporting non-serious adverse events: 0 %

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Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: See attachement



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported