Clinical trial results:
Influence of continuous administration of phenylephrine versus dobutamine on spinal oxygen saturation, measured with near-infrared spectroscopy (NIRS).

Summary

EudraCT number	2018-003687-31
Trial protocol	BE
Global end of trial date	10 November 2022

Results information

Result version number	v1 (current)
This version publication date	07 June 2024
First version publication date	07 June 2024
Summary attachment (see zip file)	Final Study Report (BC-04033_Final study report_2022-05-13.pdf) End Of Trial (BC-4033_Notification end of Trial_2017-07-16.pdf) Protocol (BC-4033_Protocol_V4_2020-11-27_Clean.docx)

Trial information

Trial identification

Sponsor protocol code	AGO/2018/005

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZ Ghent
Sponsor organisation address	C. Heymanslaan 10, Gent, Belgium, 9000
Public contact	HIRUZ, Ghent University Hospital, +32 93320500, hiruz.ctu@uzgent.be
Scientific contact	HIRUZ, Ghent University Hospital, 093320000 93320500, 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	13 May 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	10 November 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluation of the effect of continuous administration of phenylephrine or dobutamine on the spinal vasculature, by measuring spinal oxygen saturation with NIRS.

Protection of trial subjects:

See attachments

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 July 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: 36
Worldwide total number of subjects	36
EEA total number of subjects	36

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)	36
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

See attachments

Pre-assignment

Screening details:

See attachments

Period 1

Period 1 title	Main period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

see attachments

Arms

Are arms mutually exclusive?	Yes
Arm title	Phenylephrine continuous infusion

Arm description:

Phenylephrine continuous infusion

Arm type	Active comparator
Investigational medicinal product name	Phenylephrine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

See attachment

Arm title	Dobutamine continuous infusion

Arm description:

Dobutamine continuous infusion

Arm type	Active comparator
Investigational medicinal product name	Dobutamine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

See attachment

Number of subjects in period 1[1]	Phenylephrine continuous infusion	Dobutamine continuous infusion
Started	17	17
Completed	17	17

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: In total, 36 patients signed an informed consent (replacement of 2 drop-outs).

Baseline characteristics

End points

End points reporting groups

Reporting group title	Phenylephrine continuous infusion
Reporting group description: Phenylephrine continuous infusion	
Reporting group title	Dobutamine continuous infusion
Reporting group description: Dobutamine continuous infusion	

Primary: Primary

End point title	Primary[1]
End point description: Spinal oxygen saturation measured by NIRS	
End point type	Primary
End point timeframe: During the study	

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 attachments

End point values	Phenylephrine continuous infusion	Dobutamine continuous infusion		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	17		
Units: NIRS				
number (not applicable)	17	17		

Statistical analyses

No statistical analyses for this end point

Secondary: Secondary

End point title	Secondary
End point description: Cerebral oxygen saturation Deltoid muscle oxygen saturation	
End point type	Secondary
End point timeframe: During the study	

End point values	Phenylephrine continuous infusion	Dobutamine continuous infusion		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	17		
Units: oxygen saturation				
number (not applicable)	17	17		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	

Timeframe for reporting adverse events:

During the study

Adverse event reporting additional description:

See attachments

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 0 %

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 attachments

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported