Clinical trial results:
Effect of strategy for blood pressure control on cerebral oxygen balance during aortic coarctation repair: a randomized study

Summary

EudraCT number	2007-002640-19
Trial protocol	BE
Global end of trial date	15 March 2012

Results information

Result version number	v1 (current)
This version publication date	07 November 2021
First version publication date	07 November 2021

Trial information

Trial identification

Sponsor protocol code	AGO/2007/003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00535808
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	C. Heymanslaan 10, Ghent, Belgium, 9000
Public contact	HIRUZ CTU, Ghent University Hospital, 32 93320500, hiruz.ctu@uzgent.be
Scientific contact	HIRUZ CTU, Ghent University Hospital, 32 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	01 June 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 March 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

investigation of the effect of different blood pressure controlling agents on the cerebral oxygen balance between both brain hemispheres during aortic coarctation repair by using near-infrared technology

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2007
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: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	15
Infants and toddlers (28 days-23 months)	15
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Last patient last visit was on 15MAR2011

Pre-assignment

Screening details:

All neonates and infants, aged 0 – 18 year, with aortic coarctation requiring surgical correction without the additional use of cardiopulmonary bypass

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Nitroprusside

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Nitroprusside
Investigational medicinal product code	
Other name	Nitropress
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

50 mg/2 ml vial for intravenous use, 0.1 – 2 µg/kg/min. The solution must be further diluted in sterile 5% dextrose injection before infusion

Arm title	Nitroglycerine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Nitroglycerine
Investigational medicinal product code	
Other name	Solinitrina
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

50 mg/10 ml ampoule for intravenous use, 0.1 – 2 µg/kg/min

Arm title	Sevoflurane

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Sevoflurane
Investigational medicinal product code	
Other name	Sevorane
Pharmaceutical forms	Inhalation vapour
Routes of administration	Inhalation use

Dosage and administration details:

250 ml bottle, volatile anesthetic, 0.5 – 5 %

Number of subjects in period 1	Nitroprusside	Nitroglycerine	Sevoflurane
Started	10	10	10
Completed	10	10	10

Baseline characteristics

Reporting groups	
Reporting group title	Nitroprusside
Reporting group description: -	
Reporting group title	Nitroglycerine
Reporting group description: -	
Reporting group title	Sevoflurane
Reporting group description: -	

Reporting group values	Nitroprusside	Nitroglycerine	Sevoflurane
Number of subjects	10	10	10
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous			
Age of patients			
Units: days			
median	20	90	12
full range (min-max)	3 to 77	5 to 568	4 to 193
Gender categorical Units: Subjects			
Female	2	4	3
Male	8	6	7
ASA physical status Units: Subjects			
II	6	4	5
III	4	5	5
status I	0	1	0
Weight Units: kg			
median	3.6	5.1	3.3
full range (min-max)	1.4 to 5.7	3.2 to 11.3	2.0 to 8.6
BSA Units: m2			
median	0.22	0.27	0.21
full range (min-max)	0.12 to 0.28	0.2 to 0.49	0.15 to 0.39

Reporting group values	Total		

Number of subjects	30		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Age of patients			
Units: days median full range (min-max)	- -		
Gender categorical Units: Subjects			
Female	9		
Male	21		
ASA physical status Units: Subjects			
II	15		
III	14		
status I	1		
Weight Units: kg median full range (min-max)	 -		
BSA Units: m2 median full range (min-max)	 -		

End points

End points reporting groups

Reporting group title	Nitroprusside
Reporting group description: -	
Reporting group title	Nitroglycerine
Reporting group description: -	
Reporting group title	Sevoflurane
Reporting group description: -	

Primary: Max change in renal oxygen saturation

End point title	Max change in renal oxygen saturation
End point description:	
End point type	Primary
End point timeframe:	
measured during the trial	

End point values	Nitroprusside	Nitroglycerine	Sevoflurane	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: percentage				
arithmetic mean (standard deviation)	-59 (± 13)	-33 (± 22)	-43 (± 19)	

Statistical analyses

Statistical analysis title	Mean difference maximal relative change
Comparison groups	Nitroglycerine v Sevoflurane v Nitroprusside
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.04
Method	Kruskal-wallis

Primary: Max change in muscle oxygen saturation

End point title	Max change in muscle oxygen saturation
End point description:	
End point type	Primary

End point timeframe: overall trial

End point values	Nitroprusside	Nitroglycerine	Sevoflurane	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: percentage				
arithmetic mean (standard deviation)	-64 (± 17)	-34 (± 25)	-55 (± 19)	

Statistical analyses

Statistical analysis title	Max change in muscle oxygen saturation
Comparison groups	Nitroglycerine v Nitroprusside v Sevoflurane
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.014
Method	Kruskal-wallis

Primary: Decay rate renal oxygen saturation

End point title	Decay rate renal oxygen saturation
End point description:	
End point type	Primary
End point timeframe: overall trial	

End point values	Nitroprusside	Nitroglycerine	Sevoflurane	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: percentage per minute				
arithmetic mean (standard deviation)	-7.7 (± 2.7)	-3.9 (± 3.0)	-5.6 (± 3.1)	

Statistical analyses

Statistical analysis title	Decay rate renal oxygen saturation
Comparison groups	Nitroprusside v Nitroglycerine v Sevoflurane

Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.034
Method	Kruskal-wallis

Primary: Decay rate muscle oxygen saturation

End point title	Decay rate muscle oxygen saturation
End point description:	

End point type	Primary
End point timeframe: overall trial	

End point values	Nitroprusside	Nitroglycerine	Sevoflurane	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	10	
Units: percentage per minute				
arithmetic mean (standard deviation)	-9.3 (± 3.7)	-3.9 (± 2.7)	-6.2 (± 2.4)	

Statistical analyses

Statistical analysis title	Decay rate SmO2
Comparison groups	Nitroprusside v Nitroglycerine v Sevoflurane
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.003
Method	Kruskal-wallis

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: overall trial	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	CTCAE
Dictionary version	5

Frequency threshold for reporting non-serious adverse events: 5 %

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: No adverse events have been recorded during the study

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