Clinical trial results:
Influence of vasopressors on brain oxygenation and microcirculation in anesthetized patients with cerebral tumors

Summary

EudraCT number	2015-001359-60
Trial protocol	DK
Global end of trial date	29 November 2017

Results information

Result version number	v1 (current)
This version publication date	17 December 2021
First version publication date	17 December 2021

Trial information

Trial identification

Sponsor protocol code	Vasobrain01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02713087
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hospital
Sponsor organisation address	Nørrebrogade 44, Aarhus C, Denmark, 8000
Public contact	Neuroanesthesia trial info/KK, Aarhus University Hospital, 45 78463333, klaukoch@rm.dk
Scientific contact	Neuroanesthesia trial info/KK, Aarhus University Hospital, 45 78463333, klaukoch@rm.dk

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	29 November 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 November 2017
Global end of trial reached?	Yes
Global end of trial date	29 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate whether phenylephrine and ephedrine causes different alterations in microcirculation and oxygenation, as measured with magnetic resonance imaging (MRI) and positron emission tomography (PET), in anesthetized patients with brain tumors.

Two RCT rapported and attached under "more information". Only one RCT will be rapported in this system, but all details could be found in the articles attached. Twenty-four patients were included in each study, but only one study (24 patients) will bed rapported in this system.

Protection of trial subjects:

All patients were anesthetized during examination and we sought to minimize the extra time in general anesthesia. Patients were monitored according to hospital standards during anesthesia. No other measures were taken.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 August 2015
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	Denmark: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	18

From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Still only one study will be rapported in this system. The study enrolled patients in a period from september 2015 until november 2016 and included 24 patients - all recruited in the day care clinic, where they were examined before surgery.

Pre-assignment

Screening details:

Patients were screened according to in- and exclusion criteria rapported in the articles attached under "more information".

Period 1

Period 1 title	Overall period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Phenylephrine

Arm description:

One vasopressor drug were given to half of the patients in the study.

Arm type	Experimental
Investigational medicinal product name	Phenylephrine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Phenylephrine 0,1 mg/ml given until MAP > 60 or a 20% increase from baseline and until final MRI examination.

Arm title	Ephedrine

Arm description:

One vasopressor drug were given to half of the patients in the study.

Arm type	Experimental
Investigational medicinal product name	Ephedrine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Ephedrine 0,1 mg/ml given until MAP > 60 or a 20% increase from baseline and until final MRI examination.

Number of subjects in period 1	Phenylephrine	Ephedrine
Started	12	12
Completed	10	10
Not completed	2	2
Physician decision	2	2

Baseline characteristics

Reporting groups	
Reporting group title	Phenylephrine
Reporting group description:	
One vasopressor drug were given to half of the patients in the study.	
Reporting group title	Ephedrine
Reporting group description:	
One vasopressor drug were given to half of the patients in the study.	

Reporting group values	Phenylephrine	Ephedrine	Total
Number of subjects	12	12	24
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			
Units: years			
arithmetic mean	64	56	
standard deviation	± 8	± 14	-
Gender categorical			
Units: Subjects			
Female	6	6	12
Male	6	6	12

End points

End points reporting groups

Reporting group title	Phenylephrine
Reporting group description:	
One vasopressor drug were given to half of the patients in the study.	
Reporting group title	Ephedrine
Reporting group description:	
One vasopressor drug were given to half of the patients in the study.	

Primary: Difference in capillary transit time heterogeneity in the contralateral hemisphere

End point title	Difference in capillary transit time heterogeneity in the contralateral hemisphere[1]
End point description:	
End point type	Primary
End point timeframe:	
The endpoint is accesed during the MRI before surgery.	

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: All the statistical analysis can be seen in the articles attached.

End point values	Phenylephrine	Ephedrine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: second				
arithmetic mean (standard deviation)	0.2 (± 0.4)	-0.4 (± 0.3)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

From the time of anesthesia until end of surgery.

Assessment type	Systematic

Dictionary used

Dictionary name	None
Dictionary version	1.0

Reporting groups

Reporting group title	Phenylephrine

Reporting group description:

One vasopressor drug were given to half of the patients in the study.

Reporting group title	Ephedrine

Reporting group description:

One vasopressor drug were given to half of the patients in the study.

Serious adverse events	Phenylephrine	Ephedrine	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Phenylephrine	Ephedrine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 12 (0.00%)	

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: Yes - there were no adverse events rapported 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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Only one RCT has been rapported in this system as the system can not managed two RCT under the same EudraCT number.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/34344019

http://www.ncbi.nlm.nih.gov/pubmed/32482999