



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