# Clinical trial results:
# Comparison of the effect of xylometazoline and cocaine on epistaxis when administered as local vasoconstrictors prior to nasal intubation

## Summary

| | |
|---|---|
| EudraCT number | 2021-000691-11 |
| Trial protocol | DK |
| Global end of trial date | 22 March 2023 |

### Results information

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 16 October 2024 |
| First version publication date | 16 October 2024 |

## Trial information

### Trial identification

| | |
|---|---|
| Sponsor protocol code | 89303200 |

### Additional study identifiers

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT05334017 |
| WHO universal trial number (UTN) | - |

Notes:

### Sponsors

| | |
|---|---|
| Sponsor organisation name | Rigshospitalet |
| Sponsor organisation address | Blegdamsvej 3, Copenhagen, Denmark, |
| Public contact | Department of Anesthesiology, Rigshospitalet, Centre of Head and Orthopaedics, +45 35453474, anop-hoc.rigshospitalet@regionh.dk |
| Scientific contact | Department of Anesthesiology, Rigshospitalet, Centre of Head and Orthopaedics, +45 35453474, anop-hoc.rigshospitalet@regionh.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 | 15 August 2023 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 22 March 2023 |
| Global end of trial reached? | Yes |
| Global end of trial date | 22 March 2023 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The objective of this study is to compare xylometazoline and cocaine’s effect on minimizing epistaxis when administered as a local vasoconstrictor prior to nasal intubation.

Protection of trial subjects:

Covered by the Danish 'Patienterstatning'

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 08 September 2022 |
| 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: 119 |
| Worldwide total number of subjects | 119 |
| EEA total number of subjects | 119 |

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) | 110 |
| From 65 to 84 years | 8 |
| 85 years and over | 1 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Assessed for eligibility (n=275)

Excluded (n=155)
No investigator available (n=124)
Declined to participate (n=24)
Previously included (n=3)
Randomization module unavailable (n=3)
Active cocaine abuse (n=1)

Enrolled (n=120)
Excluded prior to randomization du to change of intubation method (n=1)

Randomized (n=119)

### Pre-assignment period milestones

| | |
|---|---|
| Number of subjects started | 119 |
| Number of subjects completed | 119 |

### Period 1

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

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Cocaine |

Arm description: -

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Cocaine 4% |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Nasal spray, solution |
| Routes of administration | Nasal use |

Dosage and administration details:

2 mL 4% nasal spray through diffuser

| | |
|---|---|
| **Arm title** | Xylometazoline |

Arm description: -

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Xylometazoline |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Nasal spray, solution |
| Routes of administration | Nasal use |

Dosage and administration details:
2 mL 0.05% xylometazoline as nasal spray through diffuser

| **Number of subjects in period 1** | Cocaine | Xylometazoline |
|---|---|---|
| Started | 60 | 59 |
| Completed | 60 | 59 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Cocaine |
| Reporting group description: - | |
| Reporting group title | Xylometazoline |
| Reporting group description: - | |

| Reporting group values | Cocaine | Xylometazoline | Total |
|---|---|---|---|
| Number of subjects | 60 | 59 | 119 |
| Age categorical<br>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<br>Units: years | | | |
| median | 27 | 24 | |
| inter-quartile range (Q1-Q3) | 23 to 40 | 22 to 35 | - |
| Gender categorical<br>Units: Subjects | | | |
| Female | 31 | 36 | 67 |
| Male | 29 | 23 | 52 |

## End points

| End points reporting groups | |
|---|---|
| Reporting group title | Cocaine |
| Reporting group description: - | |
| Reporting group title | Xylometazoline |
| Reporting group description: - | |

| Primary: Epistaxis | |
|---|---|
| End point title | Epistaxis |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| Immediately after nasotracheal intubation | |

| End point values | Cocaine | Xylometazoline | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 53 | 49 | | |
| Units: Yes/no | 32 | 34 | | |

### Statistical analyses

| Statistical analysis title | Fisher's exact test |
|---|---|
| Comparison groups | Cocaine v Xylometazoline |
| Number of subjects included in analysis | 102 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.41 |
| Method | Fisher exact |

## Adverse events

| Adverse events information | |
|---|---|
| Timeframe for reporting adverse events: 24 hours | |
| Assessment type | Systematic |

| Dictionary used | |
|---|---|
| Dictionary name | GCP |
| Dictionary version | 1 |

| Reporting groups | |
|---|---|
| Reporting group title | Cocaine |
| Reporting group description: - | |
| Reporting group title | Xylometazoline |
| Reporting group description: - | |

| Serious adverse events | Cocaine | Xylometazoline | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | 0 / 59 (0.00%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Desaturation | | | |
| subjects affected / exposed | 1 / 60 (1.67%) | 0 / 59 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 1 %

| Non-serious adverse events | Cocaine | Xylometazoline | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 10 / 60 (16.67%) | 14 / 59 (23.73%) | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 10 / 60 (16.67%) | 14 / 59 (23.73%) | |
| occurrences (all) | 10 | 14 | |

## 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