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 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			
median	27	24	
inter-quartile range (Q1-Q3)	23 to 40	22 to 35	-
Gender categorical 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