



Clinical trial results:

Drug test detection 24 hours after nasal administration of cocaine as a local vasoconstrictor prior to nasal intubation

Summary

EudraCT number	2021-000709-26
Trial protocol	DK
Global end of trial date	27 May 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	50510617
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05334056
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	22 November 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 May 2023
Global end of trial reached?	Yes
Global end of trial date	27 May 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 determine whether it is possible to detect traces above national cut-offs of either cocaine in saliva or its main metabolite benzoylecgonine in blood 24 hours after administering 2 ml of 40 mg/ml cocaine-saline to the nasal mucosa.

Protection of trial subjects:

Covered by the Danish 'Patienterstatningen'

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: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

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)	69
From 65 to 84 years	9
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	80
Number of subjects completed	80

Period 1

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

Arms

Arm title	Cocaine
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Cocaine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Nasal use

Dosage and administration details:

2 mL 4% cocaine solution

Number of subjects in period 1	Cocaine
Started	80
Completed	80

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
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Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	80	80	
Age categorical Units: Subjects			
Age continuous Units: years median inter-quartile range (Q1-Q3)	30 24 to 49	-	
Gender categorical Units: Subjects			
Female	39	39	
Male	41	41	

End points

End points reporting groups

Reporting group title	Cocaine
Reporting group description: -	

Primary: Drug test detection of cocaine

End point title	Drug test detection of cocaine ^[1]
End point description:	

End point type	Primary
End point timeframe:	
24 hours after drug administration	

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: Observational study.

Number and proportion with a positive test of cocaine >0.01 mg/kg in whole blood 24 h after administration (percentage; 95% CI): 2/75 (3%; 0.3%–9%)

End point values	Cocaine			
Subject group type	Reporting group			
Number of subjects analysed	75			
Units: Above cut-off of 0.01 mg/kg				
Above cut-off of 0.01 mg/kg	2			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

24 hours

Assessment type	Systematic
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Dictionary used

Dictionary name	GCP
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Dictionary version	1
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Reporting groups

Reporting group title	Cocaine
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Reporting group description: -

Serious adverse events	Cocaine		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 80 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	Cocaine		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 80 (28.75%)		
Nervous system disorders			
Headache			
subjects affected / exposed	23 / 80 (28.75%)		
occurrences (all)	23		

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