Clinical trial results:
Pharmacokinetic study of intranasal CT001 in children 1-17 years of age undergoing elective surgical procedures

Summary

EudraCT number	2021-000137-14
Trial protocol	DK
Global end of trial date	13 May 2022

Results information

Result version number	v1 (current)
This version publication date	10 May 2023
First version publication date	10 May 2023

Trial information

Trial identification

Sponsor protocol code	PDC-01-0206

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04897750
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Cessatech AS
Sponsor organisation address	Kanonbådsvej 2, Copenhagen, Denmark, 1437
Public contact	CEO, Cessatech A/S, jes.trygved@cessatech.com
Scientific contact	CEO, Cessatech A/S, jes.trygved@cessatech.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001739-PIP02-16
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	10 April 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 May 2022
Global end of trial reached?	Yes
Global end of trial date	13 May 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary objectives:
- To determine the PK profile of CT001 in children 1-2 years undergoing surgical procedures.
- To collect supplemental PK data in children >2-17 years.

Protection of trial subjects:

None

Background therapy:

None

Evidence for comparator:

No comparator

Actual start date of recruitment	19 August 2021
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: 26
Worldwide total number of subjects	26
EEA total number of subjects	26

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)	8
Children (2-11 years)	9
Adolescents (12-17 years)	9
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

26 subjects were screened for the study at one site in Denmark during the period 19-Aug-2021 until 13-May-2022. Of these 26 subjects screened 25 subjects received IMP.

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	26
Number of subjects completed	25

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Consent withdrawn by subject: 1

Period 1

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

Blinding implementation details:

Not relevant, open study

Arms

Arm title	CT001

Arm description:

Intranasal sufentanil 0,5 mcg/kg + ketamine 0,5 mg/kg, and an additional dose if needed as premedication 10 minutes before placement of a peripheral venous catheter for induction of anaesthesia.

Arm type	Experimental
Investigational medicinal product name	CT001
Investigational medicinal product code	CT001
Other name	
Pharmaceutical forms	Nasal spray
Routes of administration	Intranasal use

Dosage and administration details:

Intranasal sufentanil 0,5 mcg/kg + ketamine 0,5 mg/kg, and an additional dose if needed as premedication 10 minutes before placement of a peripheral venous catheter for induction of anaesthesia.

Number of subjects in period 1[1]	CT001
Started	25
Completed	25

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: One patient was withdrawn during screening.

Baseline characteristics

Reporting groups	
Reporting group title	CT001

Reporting group description:

Intranasal sufentanil 0,5 mcg/kg + ketamine 0,5 mg/kg, and an additional dose if needed as premedication 10 minutes before placement of a peripheral venous catheter for induction of anaesthesia.

Reporting group values	CT001	Total	
Number of subjects	25	25	
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	5.7		
standard deviation	± 4.6	-	
Gender categorical Units: Subjects			
Female	2	2	
Male	23	23	

End points

End points reporting groups

Reporting group title	CT001

Reporting group description:

Intranasal sufentanil 0,5 mcg/kg + ketamine 0,5 mg/kg, and an additional dose if needed as premedication 10 minutes before placement of a peripheral venous catheter for induction of anaesthesia.

Primary: Cmax Ketamine IN

End point title	Cmax Ketamine IN[1]

End point description:

End point type	Primary

End point timeframe:

One dosing with a optional second dose if needed

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: Not applicable

End point values	CT001			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: mg/mL				
geometric mean (geometric coefficient of variation)	0.102 (± 51.2)			

Statistical analyses

No statistical analyses for this end point

Primary: AUC0-last Ketamin IN

End point title	AUC0-last Ketamin IN[2]

End point description:

End point type	Primary

End point timeframe:

One dose with a optional second dose if needed.

Notes:

[2] - 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: Not applicable

End point values	CT001			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: mg/L*h				
geometric mean (geometric coefficient of variation)	0.152 (± 46.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Cmax Sufentanil IN

End point title	Cmax Sufentanil IN[3]

End point description:

End point type	Primary

End point timeframe:

One dose with a optional second dose if needed.

Notes:

[3] - 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: Not applicable

End point values	CT001			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: ug/mL				
geometric mean (geometric coefficient of variation)	0.086 (± 56.1)			

Statistical analyses

No statistical analyses for this end point

Primary: AUC0-last Sufentanil IN

End point title	AUC0-last Sufentanil IN[4]

End point description:

End point type	Primary

End point timeframe:

One dose with a optional second dose if needed.

Notes:

[4] - 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: Not applicable

End point values	CT001			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: ug/L*h				
geometric mean (geometric coefficient of variation)	0.136 (± 57.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pain assessment

End point title	Pain assessment

End point description:

End point type	Secondary

End point timeframe:

Pain intensity assessment before and after placement of PVC

End point values	CT001			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: Numeric scale				
least squares mean (inter-quartile range (Q1-Q3))	0 (0 to 3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Sedation assessment

End point title	Sedation assessment

End point description:

End point type	Secondary

End point timeframe:

Sedation assessment after IMP

End point values	CT001			
Subject group type	Reporting group			
Number of subjects analysed	25			
Units: subjects				
Awake and alert	0			
Minimally sedated	12			
Moderately sedated	11			
Deeply sedated	2			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse events were collected from the first dose until 24 hours after dosing.	
Adverse event reporting additional description:	
Adverse events were collected based on study personnel observations during dosing and observation on site and spontaneous reporting from subjects/parents.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24

Reporting groups	
Reporting group title	All subjects
Reporting group description:	
Events for all subjects who received at least one dose	

Serious adverse events	All subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 25 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	All subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 25 (44.00%)		
Injury, poisoning and procedural complications			
Agitation postoperative			
subjects affected / exposed	2 / 25 (8.00%)		
occurrences (all)	8		
Procedural nausea			
subjects affected / exposed	5 / 25 (20.00%)		
occurrences (all)	20		
Procedural pain			
subjects affected / exposed	4 / 25 (16.00%)		
occurrences (all)	16		

Procedural vomiting subjects affected / exposed occurrences (all)	5 / 25 (20.00%) 20		

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