



Clinical trial results: Pain relief of methoxyflurane in patients with burns Summary

EudraCT number	2020-005865-14
Trial protocol	DK
Global end of trial date	29 August 2022

Results information

Result version number	v1 (current)
This version publication date	16 September 2022
First version publication date	16 September 2022

Trial information

Trial identification

Sponsor protocol code	2020110357
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Inge Lehmanns Vej 6, Copenhagen, Denmark, DK-2100
Public contact	Dept Anaesthesia, Rigshospitalet, 45 35458043, lars.rasmussen.01@regionh.dk
Scientific contact	Dept Anaesthesia, Rigshospitalet, 61652212 35458043, lars.rasmussen.01@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	29 August 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 August 2022
Global end of trial reached?	Yes
Global end of trial date	29 August 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess pain relief of methoxyflurane in patients with burns undergoing change of wound dressing

Protection of trial subjects:

Basic pain relief provided

Background therapy:

Paracetamol, NSAID and opioids provided for basic pain relief

Evidence for comparator:

No comparator

Actual start date of recruitment	25 June 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: 12
Worldwide total number of subjects	12
EEA total number of subjects	12

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)	8
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was undertaken at Copenhagen University Hospital, Rigshospitalet, 25th of June 2021 to 31st of July 2022

Pre-assignment

Screening details:

We screened burn patients at least 18 years and able to give informed consent.

Period 1

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

Blinding implementation details:

No blinding

Arms

Arm title	Methoxyflurane
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Arm description:

Burn patients receiving methoxyflurane

Arm type	Experimental
Investigational medicinal product name	Penthrox
Investigational medicinal product code	PR1
Other name	
Pharmaceutical forms	Inhalation vapour, solution
Routes of administration	Inhalation use

Dosage and administration details:

Self administered inhalation through specific device containing 3 ml

Number of subjects in period 1	Methoxyflurane
Started	12
Completed	12

Baseline characteristics

Reporting groups

Reporting group title	Baseline
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Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	12	12	
Age categorical			
Age			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Below 65	0	0	
Adult	8	8	
Old	4	4	
Age continuous			
Age			
Units: years			
median	56		
inter-quartile range (Q1-Q3)	50 to 68	-	
Gender categorical			
Units: Subjects			
Female	4	4	
Male	8	8	

Subject analysis sets

Subject analysis set title	All
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Subject analysis set type	Full analysis
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Subject analysis set description:

All patients

Reporting group values	All		
Number of subjects	12		
Age categorical			
Age			
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		
Below 65	0		
Adult	8		
Old	4		
Age continuous			
Age			
Units: years			
median	56		
inter-quartile range (Q1-Q3)	50 to 68		
Gender categorical			
Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	Methoxyflurane
Reporting group description: Burn patients receiving methoxyflurane	
Subject analysis set title	All
Subject analysis set type	Full analysis
Subject analysis set description: All patients	

Primary: Maximal pain during the procedure

End point title	Maximal pain during the procedure ^[1]
End point description: Maximal pain as expressed by patient	
End point type	Primary
End point timeframe: During procedure with change of dressing	

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: No test done

End point values	All			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: mm				
median (inter-quartile range (Q1-Q3))	60 (37 to 80)			

Statistical analyses

No statistical analyses for this end point

Secondary: Patient satisfaction

End point title	Patient satisfaction
End point description:	
End point type	Secondary
End point timeframe: After procedure	

End point values	All			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: mm				
median (inter-quartile range (Q1-Q3))	96 (69 to 100)			

Statistical analyses

No statistical analyses for this end point

Secondary: Nurse's assessment of pain

End point title	Nurse's assessment of pain
End point description:	
End point type	Secondary
End point timeframe:	
After procedure	

End point values	All			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: mm				
median (inter-quartile range (Q1-Q3))	57 (28 to 67)			

Statistical analyses

No statistical analyses for this end point

Secondary: Oxygen saturation

End point title	Oxygen saturation
End point description:	
End point type	Secondary
End point timeframe:	
Lowest during procedure	

End point values	All			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Per cent				
median (inter-quartile range (Q1-Q3))	96 (94 to 98)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Seven days

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	2022AA
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Reporting groups

Reporting group title	All exposed
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Reporting group description:

Burn patients exposed to methoxyflurane

Serious adverse events	All exposed		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	All exposed		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 12 (8.33%)		
Gastrointestinal disorders			
Nausea	Additional description: nausea experienced after the procedure		
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Slow recruitment

Notes: