



Clinical trial results:

Can we get conscious sedation in optimal safety conditions in an emergency department, by combining dexmedetomidine with ketamine?

Summary

EudraCT number	2014-005170-11
Trial protocol	BE
Global end of trial date	01 March 2016

Results information

Result version number	v1 (current)
This version publication date	27 March 2021
First version publication date	27 March 2021

Trial information

Trial identification

Sponsor protocol code	UCLDexAlf1
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02358057
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Cliniques universitaires Saint-Luc
Sponsor organisation address	Avenue Hippocrate, 10, Brussels, Belgium, 1200
Public contact	Franck Verschuren, Cliniques universitaires Saint-Luc, +32 27648080, franck.verschuren@uclouvain.be
Scientific contact	Franck Verschuren, Cliniques universitaires Saint-Luc, +32 27648080, franck.verschuren@uclouvain.be

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	02 January 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 March 2016
Global end of trial reached?	Yes
Global end of trial date	01 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective is to determine if combinaison of dexmédétomidine and Ketamine allows a level of conscious sedation within maximum security conditions in an emergency department.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) regulations/guidelines, United States Food and Drug Administration (FDA) regulations/guidelines, and country-specific national and local laws.

Background therapy:

Patients included in the study received an infusion of dexmedetomidine via a TIVA Injectomat Agilia syringe pump, specially programmed for the injection of dexmedetomidine.

At time zero, the patient receives a bolus of 1 mcg / kg dexmedetomidine for 10 minutes.

Patients over 65 received a bolus of 0.5 mcg / kg dexmedetomidine for 10 minutes.

Then the patient will receive a continuous injection of 0.6 mcg / kg / h of dexmedetomidine

Patients

Evidence for comparator: -

Actual start date of recruitment	26 January 2015
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	Belgium: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	16
From 65 to 84 years	12
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Between October 2015 and September 2016, 30 patients were recruited from a single site in Belgium (Cliniques Universitaires Saint-Luc Bruxelles).

Pre-assignment

Screening details:

Patients arriving in the emergency room and requiring procedural sedation while meeting study inclusion criteria were approached to participate in the study. A clear and complete explanation was provided to them and an informed consent was signed by the patient.

Period 1

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

Arms

Arm title	Dexmedetomidine and Ketamine
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Arm description:

Patients included in the study received an infusion of dexmedetomidine via a TIVA Injectomat Agilia syringe pump, specially programmed for the injection of dexmedetomidine.

At time zero, the patient receives a bolus of 1 mcg / kg dexmedetomidine for 10 minutes.

Patients over 65 received a bolus of 0.5 mcg / kg dexmedetomidine for 10 minutes.

Then the patient will receive a continuous injection of 0.6 mcg / kg / h of dexmedetomidine

Arm type	Experimental
Investigational medicinal product name	Dexmedetomidine
Investigational medicinal product code	
Other name	Dexdor, Precedex
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

At time zero, the patient receives a bolus of 1 mcg / kg dexmedetomidine for 10 minutes.

Patients over 65 received a bolus of 0.5 mcg / kg dexmedetomidine for 10 minutes.

Then the patient will receive a continuous injection of 0.6 mcg / kg / h of dexmedetomidine

Investigational medicinal product name	ketamine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Patients will also receive a dose of kétamine 1 mg /kg, 1 minute before the technical act. Patients over 65 received a dose of 0.5 mg / kg

Number of subjects in period 1	Dexmedetomidine and Ketamine
Started	30
Completed	30

Baseline characteristics

Reporting groups

Reporting group title	Full study
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Reporting group description: -

Reporting group values	Full study	Total	
Number of subjects	30	30	
Age categorical			
Patients received combination of Dexmedetomidine and Ketamine			
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)	16	16	
From 65-84 years	12	12	
85 years and over	2	2	
Age continuous			
Patients received combination of Dexmedetomidine and Ketamine			
Units: years			
arithmetic mean	58.27		
standard deviation	± 21.25	-	
Gender categorical			
Patients received combination of Dexmedetomidine and Ketamine			
Units: Subjects			
Female	19	19	
Male	11	11	

End points

End points reporting groups

Reporting group title	Dexmedetomidine and Ketamine
Reporting group description:	
Patients included in the study received an infusion of dexmedetomidine via a TIVA Injectomat Agilia syringe pump, specially programmed for the injection of dexmedetomidine. At time zero, the patient receives a bolus of 1 mcg / kg dexmedetomidine for 10 minutes. Patients over 65 received a bolus of 0.5 mcg / kg dexmedetomidine for 10 minutes. Then the patient will receive a continuous injection of 0.6 mcg / kg / h of dexmedetomidine	

Primary: Ramsay score scale

End point title	Ramsay score scale ^[1]
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End point description:

1. Can we obtain an adequate level of sedation with dexmedetomidine and ketamine in an emergency department?

The Ramsay score scale will evaluate the sedation level.

The objective is to reach a score of 2 or 3 on the Ramsay score scale.

2. Can we do a procedural sedation with dexmedetomidine in optimal safety conditions in an emergency department?

The optimal safety conditions are determined by:

1. A stable blood pressure
2. A stable heart rhythm
3. No respiratory depression
4. Absence of hypoxia
5. Absence of vomiting

End point type	Primary
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End point timeframe:

The time for carrying out procedural sedation and post-sedation monitoring. A satisfaction survey was carried out by telephone one week after performing the procedural sedation.

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: Only descriptive statistics were performed

End point values	Dexmedetomidine and Ketamine			
Subject group type	Reporting group			
Number of subjects analysed	30			
Units: number				
Ramsay score 2 or 3	0			
Ramsay score 4 or 5	30			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

In the event of major side effects, the patient was monitored in the intensive care unit. In case of suspicion of inhalation with stable hemodynamic and respiratory parameters, the patient was hospitalized in the internal medicine unit for monitoring and

Adverse event reporting additional description:

In the event of a serious adverse event, the patient was treated according to international guidelines. Finally, a continuous assessment of the benefit / risk ratio was carried out throughout our study.

Assessment type	Systematic
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Dictionary used

Dictionary name	CTCAE GRADE
Dictionary version	4.03

Reporting groups

Reporting group title	Dexmedetomidine and Ketamine
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Reporting group description:

Patients received combination of Dexmedetomidine and Ketamine.

Serious adverse events	Dexmedetomidine and Ketamine		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (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	Dexmedetomidine and Ketamine		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 30 (40.00%)		
Vascular disorders			
Arterial hypertension	Additional description: During sedation		
subjects affected / exposed	7 / 30 (23.33%)		
occurrences (all)	1		
Arterial hypotension	Additional description: Complication in the recovery room		
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Orthostatism	Additional description: Complication in the recovery room		

subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Nervous system disorders			
dizziness	Additional description: Complication in the recovery room		
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Gastrointestinal disorders			
Vomiting	Additional description: Complication in the recovery room		
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Apnea with saturation	Additional description: During sedation		
subjects affected / exposed	1 / 30 (3.33%)		
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

None reported