Clinical trial results:
Offline monitoring of parallel concentrations of intravenously administered anesthetics, opiates and relaxants in breath and in blood during anesthesia - a pilot study

Summary

EudraCT number	2013-004127-36
Trial protocol	CZ
Global end of trial date	30 November 2014

Results information

Result version number	v1 (current)
This version publication date	12 August 2020
First version publication date	12 August 2020
Summary attachment (see zip file)	Summary (summary.docx)

Trial information

Trial identification

Sponsor protocol code	expir1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Podřipská nemocnice s poliklinikou
Sponsor organisation address	Alej 17. listopadu 1101, Roudnice n.L., s.r.o, Czech Republic,
Public contact	Michal Kroupa, Podřipská nemocnice s poliklinikou, Roudnice n.L., s.r.o, mudrmichalkroupa@seznam.cz
Scientific contact	Michal Kroupa, Podřipská nemocnice s poliklinikou, Roudnice n.L., s.r.o, mudrmichalkroupa@seznam.cz

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	30 November 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 November 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

pharmacokinetics

Protection of trial subjects:

Standard

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 February 2014
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	Czech Republic: 22
Worldwide total number of subjects	22
EEA total number of subjects	22

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)	22
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	22
Number of subjects completed	22

Period 1

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

Arms

Arm title	Main arm

Arm description:

All drugs used and monitored in the study were administered SKH during general anesthesia at the planned procedure. Thus, it was administered independently of the study, in a standard manner common to general anesthesia and according to SPC. Due to the clinical study, the indication and dosage during anesthesia were not altered.
Therefore, in this pilot study, which aims to determine the relationship of concentration at certain (below) time intervals, no detailed characteristics and dosages of the substances were given. These are listed in the anesthesiology textbooks and in the SPC.

Arm type	Experimental
Investigational medicinal product name	Sufentanil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection, Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

inj. and 5 µg of sufentanil or 50 µg of sufentanil

Investigational medicinal product name	Propofol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection, Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details:

Amp. á 200mg, bottle. 500mg or 1000mg. Propofol

Investigational medicinal product name	Ultiva
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection, Concentrate for solution for injection/infusion
Routes of administration	Intravenous use

Dosage and administration details: inj. á 1mg, or 2mg, or Remifentanil á 1mg, 2mg, or 5mg remifentanil	
Investigational medicinal product name	Rocuronium
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for injection, Concentrate for solution for injection/infusion
Routes of administration	Intravenous use
Dosage and administration details: inj. 50mg rocuronium	

Number of subjects in period 1	Main arm
Started	22
Completed	22

Baseline characteristics

Reporting groups

Reporting group title	Main period

Reporting group description: -

Reporting group values	Main period	Total	
Number of subjects	22	22	
Age categorical 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	22	22	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	19	19	
Male	3	3	

Subject analysis sets

Subject analysis set title	Population selection
Subject analysis set type	Full analysis

Subject analysis set description:

The study included SKH with ASA 1-2 aged 18-65 years, undergoing a planned operation of at least 30 min, where the use of any of these substances was expected. As this was a pilot study with the assumption of limited choice of SKH (small hospital with limited surgery), no other selection criterion was chosen, nor was there an effort for gender parity (a large part of SKH was anesthetized for gynecological performance and therefore in the study was the prevalence of women). A prerequisite for this was the consent of SKH to conduct the study.

Reporting group values	Population selection		
Number of subjects	22		
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	22		
85 years and over	0		

Gender categorical Units: Subjects			
Female	19		
Male	3		

End points

End points reporting groups

Reporting group title	Main arm

Reporting group description:

All drugs used and monitored in the study were administered SKH during general anesthesia at the planned procedure. Thus, it was administered independently of the study, in a standard manner common to general anesthesia and according to SPC. Due to the clinical study, the indication and dosage during anesthesia were not altered.
Therefore, in this pilot study, which aims to determine the relationship of concentration at certain (below) time intervals, no detailed characteristics and dosages of the substances were given. These are listed in the anesthesiology textbooks and in the SPC.

Subject analysis set title	Population selection
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Subject analysis set description:

The study included SKH with ASA 1-2 aged 18-65 years, undergoing a planned operation of at least 30 min, where the use of any of these substances was expected. As this was a pilot study with the assumption of limited choice of SKH (small hospital with limited surgery), no other selection criterion was chosen, nor was there an effort for gender parity (a large part of SKH was anesthetized for gynecological performance and therefore in the study was the prevalence of women). A prerequisite for this was the consent of SKH to conduct the study.

Primary: Main end point

End point title	Main end point[1]

End point description:

End point type	Primary

End point timeframe:

150 min

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: There was no comparison conducted, only one data set

End point values	Main arm			
Subject group type	Reporting group			
Number of subjects analysed	22			
Units: concentration mug/l				
number (not applicable)	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
None	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: There were no experimental drugs administrated, only standard anesthetics. Their concentration in breath was observed.

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