Clinical trial results:
Postoperative pain after anesthesia: propofol vs. sevoflurane

Summary

EudraCT number	2009-011038-82
Trial protocol	AT
Global end of trial date	13 March 2014

Results information

Result version number	v1 (current)
This version publication date	02 April 2021
First version publication date	02 April 2021

Trial information

Trial identification

Sponsor protocol code	20080926

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Währinger Gürtel 18-20, Vienn, Austria, 1090
Public contact	Univ.Klinik f. Anästhesie u. Allgem. Intensivmedizin, Medizinsche Universität Wien, 0043 140400,
Scientific contact	Univ.Klinik f. Anästhesie u. Allgem. Intensivmedizin, Medizinsche Universität Wien, 0043 140400,

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	13 March 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 March 2014
Global end of trial reached?	Yes
Global end of trial date	13 March 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

patient´s pain according to VAS score

Protection of trial subjects:

No painful or distressing examinations were done.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 November 2010
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	Austria: 90
Worldwide total number of subjects	90
EEA total number of subjects	90

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)	90
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients undergoing open vein stripping surgery were randomized to either sevoflurane or propofol anesthesia.

Pre-assignment

Screening details:

Participants were 18-75 yrs old, ASA 1-3 and had no history of chronic pain or allergies to morphine and derivates.All patients were capable of giving consent

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Propofol

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Propofol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

propofol at 3-5 mg!kg than in operfusor 2,5-3 mg!kg per hour

Arm title	Sevoflurane

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Sevoflurane
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation solution
Routes of administration	Inhalation use

Dosage and administration details:

5-6% than 1,5-2,5% in ear

Number of subjects in period 1	Propofol	Sevoflurane
Started	48	42
Completed	48	42

Baseline characteristics

Reporting groups

Reporting group title	Overall trial (overall period)

Reporting group description: -

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	90	90	
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)	90	90	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	52	52	
Male	38	38	

End points

End points reporting groups

Reporting group title	Propofol
Reporting group description: -	
Reporting group title	Sevoflurane
Reporting group description: -	

Primary: Postoperative opiod consumption

End point title	Postoperative opiod consumption
End point description:	
End point type	Primary
End point timeframe: after operation with pump	

End point values	Propofol	Sevoflurane		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	42		
Units: median				
median (standard deviation)	10 (± 6.20)	9.8 (± 4.19)		

Statistical analyses

Statistical analysis title	post operation pain
Comparison groups	Propofol v Sevoflurane
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5
Method	Wilcoxon (Mann-Whitney)

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
side effect : vomiting	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

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

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 was no serious adverse events

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