Clinical trial results:
Influence of sevoflurane and propofol on maximum muscular strength, speed of contraction and relaxation, in humans: A pilot study.

Summary

EudraCT number	2022-003737-19
Trial protocol	BE
Global end of trial date	27 April 2023

Results information

Result version number	v1 (current)
This version publication date	27 July 2024
First version publication date	27 July 2024
Summary attachment (see zip file)	Statistical Methodology (2022-003737-19 - Statistical Methodology.pdf)

Trial information

Trial identification

Sponsor protocol code	CHUB-ITF-sevo-propofol

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	CHU Brugmann
Sponsor organisation address	4 Place Arthur Van Gehuchten , Brussels, Belgium, 1020
Public contact	Anesthesiology Department, CHU Brugmann, 32 24773996, Christianerebecca.DZECHI@chu-brugmann.be
Scientific contact	Anesthesiology Department, CHU Brugmann, 32 24773996, Christianerebecca.DZECHI@chu-brugmann.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	27 April 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 April 2023
Global end of trial reached?	Yes
Global end of trial date	27 April 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

In this study, we want to measure the influence of sevoflurane and propofol on the maximum force, maximum speed of contraction and relaxation at the adductor pollicis (muscle of the thumb).

Protection of trial subjects:

Sevoflurane is an anesthetic gas routinely used during surgical procedures to maintain anesthesia in patients. Propofol is an intravenous anesthesia product used either to induce anesthesia or to maintain anesthesia during surgery. These two drugs are used in almost all standard of care anesthesia.

The study intervention consists of muscle strength measurement using the ITF (Isometric Thumb Force) device. This involves pushing with the thumb on a sensor that measures the force developed. This procedure does not cause pain or distress.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 January 2023
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: 48
Worldwide total number of subjects	48
EEA total number of subjects	48

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)	46
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were approached at the outpatient pre-anesthetic visit of the CHU Brugmann Hospital (Brussels, Belgium). The patient could decide up to the day of their surgery to participate in the study or not. Surgery dates ranged from 06 February 2023 till 27 April 2023.

Pre-assignment

Screening details:

Patients were screened at the outpatient pre-anesthetic visit of the CHU Brugmann Hospital (Brussels, Belgium) for inclusion/exclusion criteria. ICF was given and the patient could decide up to the day of their surgery to participate in the study or not.

Period 1

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

Blinding implementation details:

Patients are randomized in a 1:1 ration (block randomization of 4) to receive either sevoflurane or propofol for maintenance of anesthesia. Groups are put in sealed and opaque envelopes, opened after inclusion by the anesthesiologist in charge of the patient. The member of the study team explaining the procedure, and making the measurements, is blinded to the treatment group.

Arms

Are arms mutually exclusive?	Yes
Arm title	Sevoflurane

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Sevorane
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation vapour, liquid
Routes of administration	Inhalation use

Dosage and administration details:

4%, inhalation use

Arm title	Propofol

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Diprivan
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Emulsion for injection/infusion
Routes of administration	Infusion

Dosage and administration details:

10mg/kg/h, infusion

Notes:

[1] - The roles blinded appear to be inconsistent with a double blind trial.

Justification: This is an assessor-blinded trial. The patient is blind to the anesthetic used (sevoflurane or propofol). The anesthesiologist in charge of the patient is aware of the anesthetic used, but the staff performing the measurements of maximum force, maximum contraction speed and maximum relaxation speed of the adductor pollicis (muscle of the thumb) is blinded.

Number of subjects in period 1	Sevoflurane	Propofol
Started	24	24
Completed	20	20
Not completed	4	4
Adverse event, non-fatal	-	1
Anesthesia duration too short	3	-
Protocol deviation	1	3

Baseline characteristics

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

Reporting group values	Sevoflurane	Propofol	Total
Number of subjects	24	24	48
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	22	24	46
From 65-84 years	2	0	2
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	14	14	28
Male	10	10	20

End points

End points reporting groups

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

Primary: Preoperative maximum force

End point title	Preoperative maximum force[1]
End point description:	
End point type	Primary
End point timeframe:	
Before anesthesia by either sevoflurane or propofol	

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: The statistical analysis is detailed in the pdf file in annex.
There was no statistically significant differences, neither in the intragroup analysis (pre versus postoperative values in each group), nor in the intergroup analysis (propofol versus sevoflurane).

End point values	Sevoflurane	Propofol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: newton				
median (inter-quartile range (Q1-Q3))	44.46 (32.22 to 64.94)	45.02 (33.05 to 63.82)		

Statistical analyses

No statistical analyses for this end point

Primary: Postoperative maximum force

End point title	Postoperative maximum force[2]
End point description:	
End point type	Primary
End point timeframe:	
After anesthesia by either sevoflurane or propofol	

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: The statistical analysis is detailed in the pdf file in annex.
There was no statistically significant differences, neither in the intragroup analysis (pre versus postoperative values in each group), nor in the intergroup analysis (propofol versus sevoflurane).

End point values	Sevoflurane	Propofol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: newton				
median (inter-quartile range (Q1-Q3))	51.99 (33.39 to 64.79)	42.40 (35.37 to 56.63)		

Statistical analyses

No statistical analyses for this end point

Primary: Postoperative maximum contraction speed

End point title	Postoperative maximum contraction speed[3]

End point description:

End point type	Primary

End point timeframe:

After anesthesia by either sevoflurane or propofol

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: The statistical analysis is detailed in the pdf file in annex.
There was no statistically significant differences, neither in the intragroup analysis (pre versus postoperative values in each group), nor in the intergroup analysis (propofol versus sevoflurane).

End point values	Sevoflurane	Propofol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: newton/second				
median (inter-quartile range (Q1-Q3))	224.06 (140.47 to 414.52)	177.10 (136.36 to 252.98)		

Statistical analyses

No statistical analyses for this end point

Primary: Preoperative maximum relaxation speed

End point title	Preoperative maximum relaxation speed[4]

End point description:

End point type	Primary

End point timeframe:

Before anesthesia by either sevoflurane or propofol

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: The statistical analysis is detailed in the pdf file in annex.
There was no statistically significant differences, neither in the intragroup analysis (pre versus postoperative values in each group), nor in the intergroup analysis (propofol versus sevoflurane).

End point values	Sevoflurane	Propofol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: newton/second				
median (inter-quartile range (Q1-Q3))	-416.79 (-634.77 to -279.31)	-486.61 (-677.49 to -408.78)		

Statistical analyses

No statistical analyses for this end point

Primary: Postoperative maximum relaxation speed

End point title	Postoperative maximum relaxation speed[5]

End point description:

End point type	Primary

End point timeframe:

After anesthesia by either sevoflurane or propofol

Notes:

[5] - 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: The statistical analysis is detailed in the pdf file in annex.
There was no statistically significant differences, neither in the intragroup analysis (pre versus postoperative values in each group), nor in the intergroup analysis (propofol versus sevoflurane).

End point values	Sevoflurane	Propofol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: newton/second				
median (inter-quartile range (Q1-Q3))	-517.10 (-719.99 to -307.48)	-468.50 (-609.88 to -309.32)		

Statistical analyses

No statistical analyses for this end point

Primary: Preoperative maximum contraction speed

End point title	Preoperative maximum contraction speed[6]

End point description:

End point type	Primary

End point timeframe:

After anesthesia by either sevoflurane or propofol

Notes:

[6] - 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: The statistical analysis is detailed in the pdf file in annex.
There was no statistically significant differences, neither in the intragroup analysis (pre versus postoperative values in each group), nor in the intergroup analysis (propofol versus sevoflurane).

End point values	Sevoflurane	Propofol		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	20		
Units: Newton/second				
median (inter-quartile range (Q1-Q3))	223.49 (124.48 to 390.58)	178.19 (140.47 to 341.93)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Overall trial	
Assessment type	Systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	25.1
Reporting groups	
Reporting group title	Sevoflurane
Reporting group description: -	
Reporting group title	Propofol
Reporting group description: -	

Serious adverse events	Sevoflurane	Propofol	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	0 / 24 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Sevoflurane	Propofol	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)	1 / 24 (4.17%)	
Nervous system disorders			
Anxiety			
subjects affected / exposed	0 / 24 (0.00%)	1 / 24 (4.17%)	
occurrences (all)	0	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