Clinical trial results:
Emergence times and airway reactions in general laryngeal mask airway anesthesia: a randomized multicenter controlled trial

Summary

EudraCT number	2014-003810-96
Trial protocol	DE
Global end of trial date	11 February 2016

Results information

Result version number	v1 (current)
This version publication date	08 July 2022
First version publication date	08 July 2022

Trial information

Trial identification

Sponsor protocol code	14-073

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02322502
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	RWTH Aachen University for the Medical Falculty, represented by Clinical Trial Center Aachen (CTC-A)
Sponsor organisation address	Pauwelsstr. 30, Aachen, Germany, 52074
Public contact	Center for Translational and Clinical Trials Aachen (CTC-A), Uniklinik RWTH Aachen, +49 2418080092, ctc-a-spoqs@ukaachen.de
Scientific contact	Center for Translational and Clinical Trials Aachen (CTC-A), Uniklinik RWTH Aachen, +49 2418080092, ctc-a-spoqs@ukaachen.de

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	24 October 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 February 2016
Global end of trial reached?	Yes
Global end of trial date	11 February 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this study is to assess if desflurane is superior in order to achieve a faster emergence from anesthesia (stating the date of birth)

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation of Good Clinical Practice, the principles of the Declaration of Helsinki, as well as other applicable local ethical and legal requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 February 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	Germany: 352
Worldwide total number of subjects	352
EEA total number of subjects	352

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)	352
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment and treatment of subjects was performed in four trial centers. Overall 352 subjects were enrolled and randomized in the clinical trial in the timeframe from 26.02.2015 till 31.10.2015.

Pre-assignment

Screening details:

Overall 536 subjects were screened in four trial centers. Of those 536 subjects screened, 352 subjects met
the inclusion and exclusion criteria and were enrolled.

Period 1

Period 1 title	Anaesthesia induction till POD 1 (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Desflurane

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Suprane
Investigational medicinal product code	IMP 1
Other name	DESFLURANE
Pharmaceutical forms	Inhalation vapour, liquid
Routes of administration	Inhalation use

Dosage and administration details:

Fresh gas flow 2l/min, setting vapor to 12 vol. % until the desired end-expiratory target concentration of 0.8 MAC (minimal alveolar concentration) / 4-5 vol. % desflurane is achieved, reduction of the fresh gas flow to 500-1000ml and adjusting desflurane concentration to maintain a BIS index value between 40 and 60.

Arm title	Sevoflurane

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Sevorane
Investigational medicinal product code	IMP 2
Other name	Sevoflurane
Pharmaceutical forms	Inhalation vapour, liquid
Routes of administration	Inhalation use

Dosage and administration details:

Fresh gas flow 2l/min, setting vapor to 8 vol. % until the desired end-expiratory target concentration of 0.8 MAC / 1.2-1.4 vol. % sevoflurane is achieved, reduction of the fresh gas flow to 500-1000ml and adjusting desflurane concentration to maintain a BIS index value between 40 and 60.

Arm title	Propofol

Arm description: -

Arm type	Active comparator

Investigational medicinal product name	Propofol
Investigational medicinal product code	IMP 3
Other name	
Pharmaceutical forms	Emulsion for injection
Routes of administration	Intravenous use

Dosage and administration details:

5-7 mg kg-1 h-1 propofol adjusted to maintain a BIS index value between 40 and 60

Number of subjects in period 1	Desflurane	Sevoflurane	Propofol
Started	118	114	120
Completed	118	114	120

Baseline characteristics

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

Reporting group values	Desflurane	Sevoflurane	Propofol
Number of subjects	118	114	120
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
median	52	50	51
inter-quartile range (Q1-Q3)	37.5 to 63	36 to 60.5	31 to 64
Gender categorical Units: Subjects			
Female	52	56	55
Male	66	58	65
Smoking Units: Subjects			
Nonsmoker	62	62	79
ex-smoker	16	15	13
current smoker	37	34	26
missing data	3	3	2
ASA Units: Subjects			
Category I	44	42	40
Category II	56	61	72
Category III	15	8	7
missing data	3	3	1
No pre-existing disease Units: Subjects			
yes	46	49	56
no	69	62	63

missing data	3	3	1
Arterial hypertension Units: Subjects			
yes	33	29	36
no	82	82	83
missing data	3	3	1
Pulmonary disease Units: Subjects			
yes	3	1	1
no	112	110	118
missing data	3	3	1
Diabetes Units: Subjects			
yes	11	9	8
no	104	102	111
missing data	3	3	1
Renal disease Units: Subjects			
yes	3	1	1
no	112	110	118
missing data	3	3	1
Cerebrovascular disease Units: Subjects			
yes	1	0	0
no	114	111	119
missing data	3	3	1
Malignant disease Units: Subjects			
yes	11	10	5
no	104	101	114
missing data	3	3	1
Height Units: cm			
arithmetic mean	172.7	172.6	172.4
standard deviation	± 9.7	± 9.2	± 9.1
Weight Units: kg			
arithmetic mean	78.5	79.2	78.2
standard deviation	± 13	± 14.1	± 13.6
BMI Units: kg/m²			
arithmetic mean	26.3	26.5	26.2
standard deviation	± 3.7	± 3.7	± 3.6
Current smokers - Pack years Units: cigarrette pack years			
arithmetic mean	18.9	17.8	16.1
standard deviation	± 12	± 19.7	± 16

Reporting group values	Total		
Number of subjects	352		

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	0		
85 years and over	0		
Age continuous Units: years			
median			
inter-quartile range (Q1-Q3)	-		
Gender categorical Units: Subjects			
Female	163		
Male	189		
Smoking Units: Subjects			
Nonsmoker	203		
ex-smoker	44		
current smoker	97		
missing data	8		
ASA Units: Subjects			
Category I	126		
Category II	189		
Category III	30		
missing data	7		
No pre-existing disease Units: Subjects			
yes	151		
no	194		
missing data	7		
Arterial hypertension Units: Subjects			
yes	98		
no	247		
missing data	7		
Pulmonary disease Units: Subjects			
yes	5		
no	340		
missing data	7		
Diabetes Units: Subjects			
yes	28		
no	317		

missing data	7		
Renal disease Units: Subjects			
yes	5		
no	340		
missing data	7		
Cerebrovascular disease Units: Subjects			
yes	1		
no	344		
missing data	7		
Malignant disease Units: Subjects			
yes	26		
no	319		
missing data	7		
Height Units: cm			
arithmetic mean			
standard deviation	-		
Weight Units: kg			
arithmetic mean			
standard deviation	-		
BMI Units: kg/m²			
arithmetic mean			
standard deviation	-		
Current smokers - Pack years Units: cigarrette pack years			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

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

Primary: Time to state date of birth (TSB)

End point title	Time to state date of birth (TSB)
End point description:	

End point type	Primary
End point timeframe:	
Anaesthesia induction till POD 1	

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[1]	111[2]	118[3]	
Units: minute				
arithmetic mean (standard deviation)	8.1 (± 3.6)	10.1 (± 4.0)	9.8 (± 5.1)	

Notes:

[1] - 4 missing data

[2] - 3 missing data

[3] - 2 missing data

Statistical analyses

Statistical analysis title	Analysis TSB
Comparison groups	Desflurane v Propofol v Sevoflurane
Number of subjects included in analysis	343
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	ANOVA

Secondary: Intraoperative coughs

End point title	Intraoperative coughs
End point description:	

End point type	Secondary

End point timeframe:
Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
yes	4	1	2	
no	110	110	117	
missing data	4	3	1	

Statistical analyses

Statistical analysis title	Analysis intraoperative coughs
Comparison groups	Desflurane v Sevoflurane v Propofol
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.26
Method	Cochran-Mantel-Haenszel

Secondary: Intraoperative laryngospasm

End point title	Intraoperative laryngospasm

End point description:

End point type	Secondary

End point timeframe:
Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
yes	4	3	2	
no	110	108	117	
missing data	4	3	1	

Statistical analyses

Statistical analysis title	Analysis intraoperative laryngospasm
Comparison groups	Desflurane v Sevoflurane v Propofol
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.62
Method	Cochran-Mantel-Haenszel

Secondary: Cough at emergence

End point title	Cough at emergence

End point description:

End point type	Secondary

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
yes	1	0	0	
no	113	111	118	
missing data	4	3	2	

Statistical analyses

Statistical analysis title	Analysis cough at emergence
Comparison groups	Desflurane v Sevoflurane v Propofol
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.38
Method	Cochran-Mantel-Haenszel

Secondary: Laryngospasms at emergence

End point title	Laryngospasms at emergence

End point description:

End point type	Secondary

End point timeframe:
Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
yes	2	0	0	
no	112	111	119	
missing data	4	3	1	

Statistical analyses

Statistical analysis title	Analysis laryngospasm at emergence
Comparison groups	Desflurane v Sevoflurane v Propofol
Number of subjects included in analysis	352
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.08
Method	Cochran-Mantel-Haenszel

Secondary: Time to remove laryngeal mask (TLR)

End point title	Time to remove laryngeal mask (TLR)

End point description:

End point type	Secondary

End point timeframe:
Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[4]	111[5]	118[6]	
Units: minute				
arithmetic mean (standard deviation)	6.9 (± 3.3)	8.7 (± 3.9)	8.2 (± 4.1)	

Notes:
[4] - 4 missing data
[5] - 3 missing data
[6] - 2 missing data

Statistical analyses

Statistical analysis title	Analysis TLR
Comparison groups	Desflurane v Sevoflurane v Propofol
Number of subjects included in analysis	343
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANOVA

Secondary: Time to open eyes on command (TOE)

End point title	Time to open eyes on command (TOE)

End point description:

End point type	Secondary

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[7]	111[8]	119[9]	
Units: minute				
arithmetic mean (standard deviation)	6.8 (± 3.5)	8.6 (± 4.1)	8.0 (± 4.4)	

Notes:

[7] - 4 missing data

[8] - 3 missing data

[9] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis TOE
Comparison groups	Sevoflurane v Desflurane v Propofol
Number of subjects included in analysis	344
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	ANOVA

Secondary: Time to respond to command (TRC)

End point title	Time to respond to command (TRC)

End point description:

End point type	Secondary

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[10]	111[11]	119[12]	
Units: minute				
arithmetic mean (standard deviation)	7.54 (± 3.6)	9.6 (± 4.1)	9.1 (± 4.9)	

Notes:

[10] - 4 missing data

[11] - 3 missing data

[12] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis TRC
Comparison groups	Desflurane v Sevoflurane v Propofol
Number of subjects included in analysis	344
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	ANOVA

Secondary: Time to state full name on command (TSN)

End point title	Time to state full name on command (TSN)

End point description:

End point type	Secondary

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[13]	111[14]	119[15]	
Units: minute				
arithmetic mean (standard deviation)	8.0 (± 3.6)	9.9 (± 4.0)	9.7 (± 5.1)	

Notes:

[13] - 4 missing data

[14] - 3 missing data

[15] - 1 missing data

Statistical analyses

Statistical analysis title	Analysis TSN
Comparison groups	Desflurane v Sevoflurane v Propofol

Number of subjects included in analysis	344
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.01
Method	ANOVA

Secondary: Recovery index

End point title	Recovery index

End point description:

End point type	Secondary

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[16]	111[17]	118[18]	
Units: none				
arithmetic mean (standard deviation)	0.6 (± 0.3)	0.5 (± 0.6)	0.6 (± 0.7)	

Notes:

[16] - 4 missing data

[17] - 3 missing data

[18] - 2 missing data

Statistical analyses

Statistical analysis title	Analysis recovery index
Comparison groups	Sevoflurane v Desflurane
Number of subjects included in analysis	225
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.22
upper limit	0.01

Statistical analysis title	Analysis recovery index
Comparison groups	Propofol v Desflurane

Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.16
upper limit	0.08

Other pre-specified: Depth of anaesthesia (BIS)

End point title	Depth of anaesthesia (BIS)

End point description:

End point type	Other pre-specified

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[19]	111[20]	118[21]	
Units: none				
arithmetic mean (standard deviation)	42.2 (± 13.6)	46.0 (± 14.1)	43.4 (± 14.8)	

Notes:

[19] - 4 missing data

[20] - 3 missing data

[21] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Non Invasive Blood Pressure (NIBP) - systolic

End point title	Non Invasive Blood Pressure (NIBP) - systolic

End point description:

End point type	Other pre-specified

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[22]	111[23]	118[24]	
Units: mmHg				
arithmetic mean (standard deviation)	101.2 (± 18.9)	99.0 (± 17.0)	103.9 (± 18.9)	

Notes:

[22] - 4 missing data

[23] - 3 missing data

[24] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Non Invasive Blood Pressure (NIBP) - diastolic

End point title	Non Invasive Blood Pressure (NIBP) - diastolic

End point description:

End point type	Other pre-specified

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[25]	111[26]	118[27]	
Units: mmHg				
arithmetic mean (standard deviation)	57.5 (± 11.7)	58.0 (± 12.1)	61.0 (± 12.1)	

Notes:

[25] - 4 missing data

[26] - 3 missing data

[27] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Heart rate

End point title	Heart rate

End point description:

End point type	Other pre-specified

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[28]	111[29]	118[30]	
Units: bpm				
arithmetic mean (standard deviation)	57.6 (± 11.1)	57.0 (± 10.2)	56.8 (± 11.1)	

Notes:

[28] - 4 missing data

[29] - 3 missing data

[30] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Requirement of catecholamines - epinephrine & norepinephrine

End point title	Requirement of catecholamines - epinephrine & norepinephrine

End point description:

End point type	Other pre-specified

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[31]	111[32]	118[33]	
Units: µg				
arithmetic mean (standard deviation)				
epinephrine	0.5 (± 4.0)	0 (± 0)	1.0 (± 6.9)	
norepinephrine	40.4 (± 113.6)	27.4 (± 83.0)	19.5 (± 99.2)	

Notes:

[31] - 4 missing data

[32] - 3 missing data

[33] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Requirement of catecholamines - caphedrine & theoadrenaline

End point title	Requirement of catecholamines - caphedrine & theoadrenaline

End point description:

Total amount of the mixture 2 ml caphedrine 200 mg and theoadrenaline 10 mg ad 8 ml sodium chloride

End point type	Other pre-specified

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[34]	111[35]	118[36]	
Units: ml				
arithmetic mean (standard deviation)	1.3 (± 2.2)	1.4 (± 3.0)	0.9 (± 2.1)	

Notes:

[34] - 4 missing data

[35] - 3 missing data

[36] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Airway pressures

End point title	Airway pressures

End point description:

End point type	Other pre-specified

End point timeframe:

Anaesthesia induction till POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[37]	111[38]	118[39]	
Units: kPa				
arithmetic mean (standard deviation)				
Peak Pressure	1.6 (± 0.4)	1.5 (± 0.4)	1.5 (± 0.3)	
Plateau Pressure	1.2 (± 0.4)	1.1 (± 0.4)	1.1 (± 0.4)	
Positive End-Expiratory Pressure	0.3 (± 0.2)	0.3 (± 0.2)	0.3 (± 0.2)	

Notes:

[37] - 4 missing data

[38] - 3 missing data

[39] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: End-expiratory carbon dioxide

End point title	End-expiratory carbon dioxide

End point description:

End point type	Other pre-specified

End point timeframe:

Positive EndExpiratory Pressure

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[40]	111[41]	118[42]	
Units: kPa				
arithmetic mean (standard deviation)	5.1 (± 0.7)	5.1 (± 0.7)	4.9 (± 0.5)	

Notes:

[40] - 4 missing data

[41] - 3 missing data

[42] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Aldrete score ≥ 9

End point title	Aldrete score ≥ 9

End point description:

End point type	Other pre-specified

End point timeframe:

5 min after LMA removal

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
yes	94	72	74	
no	20	39	41	
missing data	4	3	2	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: VAS pain score

End point title	VAS pain score

End point description:

End point type	Other pre-specified

End point timeframe:

in the PACU

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[43]	111[44]	118[45]	
Units: score from 0-100				
arithmetic mean (standard deviation)	28.8 (± 24.3)	27.7 (± 23.2)	25.2 (± 20.7)	

Notes:

[43] - 4 missing data

[44] - 3 missing data

[45] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Frequency of vomiting

End point title	Frequency of vomiting

End point description:

End point type	Other pre-specified

End point timeframe:

in the PACU

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
yes	3	1	0	
no	111	110	118	
missing data	4	3	2	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Time to readiness to be discharged from PACU (Aldreete score ≥ 9)

End point title	Time to readiness to be discharged from PACU (Aldreete score ≥ 9)

End point description:

End point type	Other pre-specified

End point timeframe: in the PACU

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[46]	111[47]	118[48]	
Units: min				
arithmetic mean (standard deviation)	8.1 (± 10.0)	11.1 (± 10.1)	13.3 (± 16.1)	

Notes:

[46] - 4 missing data

[47] - 3 missing data

[48] - 2 missing data

Statistical analyses

Statistical analysis title	Analysis readiness - desflurane vs sevoflurane
Comparison groups	Desflurane v Sevoflurane
Number of subjects included in analysis	225
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.4
upper limit	6.3

Statistical analysis title	Analysis readiness - desflurane vs propofol
Comparison groups	Propofol v Desflurane
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	8.2

Other pre-specified: Total amount of additional applied propofol as rescue medication

End point title	Total amount of additional applied propofol as rescue

	medication

End point description:

End point type	Other pre-specified

End point timeframe:
during surgery

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[49]	111[50]	118[51]	
Units: mg				
arithmetic mean (standard deviation)	9.8 (± 44.4)	5.9 (± 17.7)	9.7 (± 50.8)	

Notes:
[49] - 4 missing data
[50] - 3 missing data
[51] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Amount of wasted propofol

End point title	Amount of wasted propofol

End point description:

End point type	Other pre-specified

End point timeframe:
during surgery

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[52]	111[53]	118[54]	
Units: mg	0	0	220	

Notes:
[52] - 4 missing data
[53] - 3 missing data
[54] - 2 missing data

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Intraoperative remifentanil dose

End point title	Intraoperative remifentanil dose

End point description:

End point type	Other pre-specified
End point timeframe: during surgery	

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[55]	111[56]	118[57]	
Units: µg kg-1 min-1				
arithmetic mean (standard deviation)	0.15 (± 0.1)	0.15 (± 0.1)	0.15 (± 0.1)	

Notes:
[55] - 4 missing data
[56] - 3 missing data
[57] - 2 missing data

Statistical analyses

Statistical analysis title	Analysis Remifentanil - desflurane vs sevoflurane
Comparison groups	Desflurane v Sevoflurane
Number of subjects included in analysis	225
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.0002
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.006
upper limit	0.005

Statistical analysis title	Analysis Remifentanil - desflurane vs propofol
Comparison groups	Desflurane v Propofol
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	0.003
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.002
upper limit	0.009

Other pre-specified: Duration of anaesthesia

End point title	Duration of anaesthesia

End point description:

End point type	Other pre-specified

End point timeframe:
during surgery

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[58]	111[59]	118[60]	
Units: min				
arithmetic mean (standard deviation)	60.0 (± 34.4)	53.7 (± 28.4)	57.8 (± 28.6)	

Notes:
[58] - 4 missing data
[59] - 3 missing data
[60] - 2 missing data

Statistical analyses

Statistical analysis title	Analysis anaesthesia - desflurane vs sevoflurane
Comparison groups	Sevoflurane v Desflurane
Number of subjects included in analysis	225
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-6.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.1
upper limit	1.8

Statistical analysis title	Analysis anaesthesia - desflurane vs propofol
Comparison groups	Propofol v Desflurane
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	7

Other pre-specified: Surgery duration	
End point title	Surgery duration
End point description:	
End point type	Other pre-specified
End point timeframe: during surgery	

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[61]	111[62]	118[63]	
Units: min				
arithmetic mean (standard deviation)	45.7 (± 32.5)	40.1 (± 25.8)	39.6 (± 27.7)	

Notes:
[61] - 4 missing data
[62] - 3 missing data
[63] - 2 missing data

Statistical analyses

Statistical analysis title	Analysis surgery - desflurane vs sevoflurane
Comparison groups	Sevoflurane v Desflurane
Number of subjects included in analysis	225
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.1
upper limit	1.8

Statistical analysis title	Analysis surgery - desflurane vs propofol
Comparison groups	Propofol v Desflurane
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.6
upper limit	2.2

Other pre-specified: PQRS cognitive domain - surgery day

End point title	PQRS cognitive domain - surgery day

End point description:

End point type	Other pre-specified

End point timeframe:
surgery day

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not recovered	20	26	31	
recovered	73	65	64	
no data	25	23	25	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: PQRS cognitive domain - POD 1

End point title	PQRS cognitive domain - POD 1

End point description:

End point type	Other pre-specified

End point timeframe:
POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not recovered	8	6	13	
recovered	76	80	80	
no data	34	28	27	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: PQRS nociceptive domain - surgery day

End point title	PQRS nociceptive domain - surgery day

End point description:

End point type	Other pre-specified

End point timeframe:

surgery day

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not recovered	79	66	57	
recovered	35	45	49	
no data	4	3	4	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: PQRS nociceptive domain - POD 1

End point title	PQRS nociceptive domain - POD 1

End point description:

End point type	Other pre-specified

End point timeframe:

POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not recovered	57	46	51	
recovered	54	60	64	
no data	7	8	5	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: PQRS emotive domain - surgery day

End point title	PQRS emotive domain - surgery day

End point description:

End point type	Other pre-specified

End point timeframe:

surgery day

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not recovered	22	19	12	
recovered	92	92	104	
no data	4	3	4	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: PQRS emotive domain - POD 1

End point title	PQRS emotive domain - POD 1

End point description:

End point type	Other pre-specified

End point timeframe:

POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not recovered	18	9	11	
recovered	93	97	104	
no data	7	8	5	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: PQRS physiological domain - surgery day

End point title	PQRS physiological domain - surgery day

End point description:

End point type	Other pre-specified

End point timeframe:

surgery day

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not recovered	37	45	46	
recovered	77	66	70	
no data	4	3	4	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: PQRS ADL domain - POD 1

End point title	PQRS ADL domain - POD 1

End point description:

End point type	Other pre-specified

End point timeframe:

POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not recovered	25	18	20	
recovered	85	88	94	
no data	8	8	6	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: PQRS all domains - surgery day

End point title	PQRS all domains - surgery day

End point description:

End point type	Other pre-specified

End point timeframe:

surgery day

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not recovered	93	90	92	
recovered	17	17	19	
no data	8	7	9	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: PQRS all domains - POD 1

End point title	PQRS all domains - POD 1

End point description:

End point type	Other pre-specified

End point timeframe:

POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not recovered	79	61	67	
recovered	25	33	37	
no data	14	20	16	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: PQRS overall patient perspective - POD 1

End point title	PQRS overall patient perspective - POD 1

End point description:

End point type	Other pre-specified

End point timeframe:

POD 1

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	118	114	120	
Units: subjects				
not at all impacted	27	29	40	
minimally impacted	23	21	23	
moderately impacted	15	23	17	
severely impacted	16	12	14	
completely impacted	21	17	17	
no data	16	12	9	

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Intraoperative piritramide

End point title	Intraoperative piritramide

End point description:

End point type	Other pre-specified

End point timeframe:

during surgery

End point values	Desflurane	Sevoflurane	Propofol	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114[64]	111[65]	118[66]	
Units: mg				
arithmetic mean (standard deviation)	5.5 (± 2.5)	5.2 (± 2.6)	4.7 (± 2.4)	

Notes:
[64] - 4 missing data
[65] - 3 missing data
[66] - 2 missing data

Statistical analyses

Statistical analysis title	Analysis piritramide - desflurane vs sevoflurane
Comparison groups	Sevoflurane v Desflurane
Number of subjects included in analysis	225
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.7
upper limit	0.4

Statistical analysis title	Analysis piritramide - desflurane vs propofol
Comparison groups	Propofol v Desflurane
Number of subjects included in analysis	232
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Mean difference (final values)
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	0

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 2 days	
Assessment type	Systematic
Dictionary used	
Dictionary name	none
Dictionary version	0
Reporting groups	
Reporting group title	Desflurane
Reporting group description: -	
Reporting group title	Sevoflurane
Reporting group description: -	
Reporting group title	Propofol
Reporting group description: -	

Serious adverse events	Desflurane	Sevoflurane	Propofol
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 118 (1.69%)	1 / 114 (0.88%)	1 / 120 (0.83%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
Hypotonia			
subjects affected / exposed	2 / 118 (1.69%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 118 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Desflurane	Sevoflurane	Propofol
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 118 (36.44%)	40 / 114 (35.09%)	38 / 120 (31.67%)
Injury, poisoning and procedural complications			

Displacement of laryngeal mask, hypotonia, bradycardia			
subjects affected / exposed	0 / 118 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
Intraoperative cough			
subjects affected / exposed	4 / 118 (3.39%)	1 / 114 (0.88%)	2 / 120 (1.67%)
occurrences (all)	6	2	3
intraoperative laryngospasm			
subjects affected / exposed	4 / 118 (3.39%)	3 / 114 (2.63%)	2 / 120 (1.67%)
occurrences (all)	5	3	2
Cough at emergence			
subjects affected / exposed	1 / 118 (0.85%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
Laryngospasm at emergence			
subjects affected / exposed	2 / 118 (1.69%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	2	0	0
Cardiac disorders			
AV Block IIA			
subjects affected / exposed	0 / 118 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
Bradycardia			
subjects affected / exposed	10 / 118 (8.47%)	7 / 114 (6.14%)	8 / 120 (6.67%)
occurrences (all)	10	7	8
Hypertension			
subjects affected / exposed	1 / 118 (0.85%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	1	0	1
Hypertension intraoperative			
subjects affected / exposed	0 / 118 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	24 / 118 (20.34%)	27 / 114 (23.68%)	22 / 120 (18.33%)
occurrences (all)	24	27	23
Hypotension intraoperative			
subjects affected / exposed	1 / 118 (0.85%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
Hypotonia intraoperative			

subjects affected / exposed	0 / 118 (0.00%)	1 / 114 (0.88%)	1 / 120 (0.83%)
occurrences (all)	0	1	1
Nervous system disorders			
postoperative agitation			
subjects affected / exposed	0 / 118 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Carbon dioxide increased			
subjects affected / exposed	0 / 118 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Postoperative nausea and vomiting			
subjects affected / exposed	1 / 118 (0.85%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	1	1	0
Shivering			
subjects affected / exposed	1 / 118 (0.85%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	1	0	1
Vomiting			
subjects affected / exposed	1 / 118 (0.85%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
perforated uterus			
subjects affected / exposed	0 / 118 (0.00%)	1 / 114 (0.88%)	0 / 120 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	1 / 118 (0.85%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
Intubation			
subjects affected / exposed	1 / 118 (0.85%)	0 / 114 (0.00%)	0 / 120 (0.00%)
occurrences (all)	1	0	0
Singultus			
subjects affected / exposed	0 / 118 (0.00%)	0 / 114 (0.00%)	1 / 120 (0.83%)
occurrences (all)	0	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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/29916859