# 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<br>Units: Subjects | | | |
| In utero<br>Preterm newborn infants (gestational age < 37 wks)<br>Newborns (0-27 days)<br>Infants and toddlers (28 days-23 months)<br>Children (2-11 years)<br>Adolescents (12-17 years)<br>Adults (18-64 years)<br>From 65-84 years<br>85 years and over | | | |
| Age continuous<br>Units: years | | | |
| median | 52 | 50 | 51 |
| inter-quartile range (Q1-Q3) | 37.5 to 63 | 36 to 60.5 | 31 to 64 |
| Gender categorical<br>Units: Subjects | | | |
| Female | 52 | 56 | 55 |
| Male | 66 | 58 | 65 |
| Smoking<br>Units: Subjects | | | |
| Nonsmoker | 62 | 62 | 79 |
| ex-smoker | 16 | 15 | 13 |
| current smoker | 37 | 34 | 26 |
| missing data | 3 | 3 | 2 |
| ASA<br>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<br>Units: Subjects | | | |
| yes | 46 | 49 | 56 |
| no | 69 | 62 | 63 |

| | | | |
|---|---|---|---|
| missing data | 3 | 3 | 1 |
| Arterial hypertension<br>Units: Subjects | | | |
| yes | 33 | 29 | 36 |
| no | 82 | 82 | 83 |
| missing data | 3 | 3 | 1 |
| Pulmonary disease<br>Units: Subjects | | | |
| yes | 3 | 1 | 1 |
| no | 112 | 110 | 118 |
| missing data | 3 | 3 | 1 |
| Diabetes<br>Units: Subjects | | | |
| yes | 11 | 9 | 8 |
| no | 104 | 102 | 111 |
| missing data | 3 | 3 | 1 |
| Renal disease<br>Units: Subjects | | | |
| yes | 3 | 1 | 1 |
| no | 112 | 110 | 118 |
| missing data | 3 | 3 | 1 |
| Cerebrovascular disease<br>Units: Subjects | | | |
| yes | 1 | 0 | 0 |
| no | 114 | 111 | 119 |
| missing data | 3 | 3 | 1 |
| Malignant disease<br>Units: Subjects | | | |
| yes | 11 | 10 | 5 |
| no | 104 | 101 | 114 |
| missing data | 3 | 3 | 1 |
| Height<br>Units: cm | | | |
| arithmetic mean | 172.7 | 172.6 | 172.4 |
| standard deviation | ± 9.7 | ± 9.2 | ± 9.1 |
| Weight<br>Units: kg | | | |
| arithmetic mean | 78.5 | 79.2 | 78.2 |
| standard deviation | ± 13 | ± 14.1 | ± 13.6 |
| BMI<br>Units: kg/m² | | | |
| arithmetic mean | 26.3 | 26.5 | 26.2 |
| standard deviation | ± 3.7 | ± 3.7 | ± 3.6 |
| Current smokers - Pack years<br>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<br>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<br>Units: years | | | |
| median | | | |
| inter-quartile range (Q1-Q3) | - | | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 163 | | |
| Male | 189 | | |
| Smoking<br>Units: Subjects | | | |
| Nonsmoker | 203 | | |
| ex-smoker | 44 | | |
| current smoker | 97 | | |
| missing data | 8 | | |
| ASA<br>Units: Subjects | | | |
| Category I | 126 | | |
| Category II | 189 | | |
| Category III | 30 | | |
| missing data | 7 | | |
| No pre-existing disease<br>Units: Subjects | | | |
| yes | 151 | | |
| no | 194 | | |
| missing data | 7 | | |
| Arterial hypertension<br>Units: Subjects | | | |
| yes | 98 | | |
| no | 247 | | |
| missing data | 7 | | |
| Pulmonary disease<br>Units: Subjects | | | |
| yes | 5 | | |
| no | 340 | | |
| missing data | 7 | | |
| Diabetes<br>Units: Subjects | | | |
| yes | 28 | | |
| no | 317 | | |

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