



Clinical trial results:

The effect of desflurane versus Sevoflurane on postoperative recovery in patients undergoing minor- to moderate-risk noncardiac surgery - a prospective double-blinded randomized clinical trial

Summary

EudraCT number	2022-000556-11
Trial protocol	AT
Global end of trial date	01 June 2023

Results information

Result version number	v1 (current)
This version publication date	18 October 2024
First version publication date	18 October 2024
Summary attachment (see zip file)	Publication (1-s2.0-S0952818024002058-main.pdf) SAE Report (RAPID_SAE.xlsx)

Trial information

Trial identification

Sponsor protocol code	RAPID_01
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05331027
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Head Office, Department of Anaesthesia, Intensive Care Medicine and Pain Medicine, 0043 4040041020, sekretariat-anaesthesie@meduniwien.ac.at
Scientific contact	Head Office, Department of Anaesthesia, Intensive Care Medicine and Pain Medicine, 0043 4040041020, sekretariat-anaesthesie@meduniwien.ac.at

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	25 August 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 June 2023
Global end of trial reached?	Yes
Global end of trial date	01 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Our primary outcome will be the time (in minutes) from discontinuation of volatile anesthetic at the end of surgery until a modified Aldrete score of ≥ 12 points will be reached. We will start to assess postoperative recovery using the modified Aldrete score after arrival at the postoperative care unit (PACU) and thereafter in five minutes intervals. The score consists of 7 modalities (Activity, Respiration, Circulation, Consciousness, Oxygenation, Pain and Emetic Symptoms) with a score of 0-2 points in each criterion.

Protection of trial subjects:

Patients received desflurane or sevoflurane for general anesthesia. Both anesthetics are commonly used for anesthesia. Thus, there is a low risk for subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 April 2022
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 190
Worldwide total number of subjects	190
EEA total number of subjects	190

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)	0
From 65 to 84 years	176

85 years and over	14
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Subject disposition

Recruitment

Recruitment details:

Study personnel screened surgical schedule a day before surgery. If patients meeting the inclusion criteria a study physician performed informed consent also a day before surgery.

Pre-assignment

Screening details:

Patients were eligible if they were at least 65 years undergoing a minor- to moderate-risk noncardiac surgery.

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Subjects were not aware of the allocated randomization.

Arms

Are arms mutually exclusive?	Yes
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Arm title	Desflurane
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Arm description:

Patients randomly assigned to desflurane received desflurane for maintenance of anesthesia after endotracheal intubation.

Arm type	Experimental
Investigational medicinal product name	Desflurane
Investigational medicinal product code	N01AB07
Other name	
Pharmaceutical forms	Inhalation vapour
Routes of administration	Inhalation use

Dosage and administration details:

Maximum of 15% inspiratory concentration %(V/V) percent volume/volume

Arm title	Sevoflurane
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Arm description:

Patients randomly assigned to sevoflurane received sevoflurane for general anesthesia after endotracheal intubation.

Arm type	Active comparator
Investigational medicinal product name	Sevoflurane
Investigational medicinal product code	N01AB08
Other name	
Pharmaceutical forms	Inhalation vapour
Routes of administration	Inhalation use

Dosage and administration details:

maximum of 6% inspiratory concentration %(V/V) percent volume/volume

Number of subjects in period 1	Desflurane	Sevoflurane
Started	95	95
Completed	95	95

Period 2

Period 2 title	Intraoperative
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Subject was unaware of the randomly assigned group.

Arms

Are arms mutually exclusive?	Yes
Arm title	Sevoflurane

Arm description:

Patients randomly assigned to sevoflurane received sevoflurane for general anesthesia.

Arm type	Active comparator
Investigational medicinal product name	Sevoflurane
Investigational medicinal product code	N01AB08
Other name	
Pharmaceutical forms	Inhalation vapour
Routes of administration	Inhalation use

Dosage and administration details:

maximum concentration of 6%, %(V/V) percent volume/volume

Arm title	Desflurane
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Arm description:

Patients randomly assigned to desflurane received desflurane for general anesthesia.

Arm type	Experimental
Investigational medicinal product name	Desflurane
Investigational medicinal product code	N01AB07
Other name	
Pharmaceutical forms	Inhalation vapour
Routes of administration	Inhalation use

Dosage and administration details:

maximum of 15% inspiratory concentration %(V/V) percent volume/volume

Number of subjects in period 2	Sevoflurane	Desflurane
Started	95	95
Completed	95	95

Period 3

Period 3 title	Outcome assessment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Single blind ^[1]
Roles blinded	Subject, Assessor

Blinding implementation details:

Outcome assessor and subject were unaware of the randomly assigned group.

Arms

Are arms mutually exclusive?	Yes
Arm title	Desflurane

Arm description:

Patients randomly assigned to desflurane received desflurane for maintenance of anesthesia after endotracheal intubation.

Arm type	Experimental
Investigational medicinal product name	Desflurane
Investigational medicinal product code	N01AB07
Other name	
Pharmaceutical forms	Inhalation vapour
Routes of administration	Inhalation use

Dosage and administration details:

Maximum of 15% inspiratory concentration %(V/V) percent volume/volume

Arm title	Sevoflurane
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Arm description:

Patients randomly assigned to sevoflurane received sevoflurane for general anesthesia after endotracheal intubation.

Arm type	Active comparator
Investigational medicinal product name	Sevoflurane
Investigational medicinal product code	N01AB08
Other name	
Pharmaceutical forms	Inhalation vapour
Routes of administration	Inhalation use

Dosage and administration details:

maximum of 6% inspiratory concentration %(V/V) percent volume/volume

Notes:

[1] - The number of roles blinded appears inconsistent with a single blinded trial. It is expected that there will be one role blinded in a single blind trial.

Justification: Only observer were blinded, treating physicians were not blinded.

Number of subjects in period 3	Desflurane	Sevoflurane
Started	95	95
Completed	95	95

Baseline characteristics

Reporting groups

Reporting group title	Desflurane
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Reporting group description:

Patients randomly assigned to desflurane received desflurane for maintenance of anesthesia after endotracheal intubation.

Reporting group title	Sevoflurane
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Reporting group description:

Patients randomly assigned to sevoflurane received sevoflurane for general anesthesia after endotracheal intubation.

Reporting group values	Desflurane	Sevoflurane	Total
Number of subjects	95	95	190
Age categorical			
Units: Subjects			
From 65-84 years	88	88	176
85 years and over	7	7	14
Age continuous			
Units: years			
median	73	73	
inter-quartile range (Q1-Q3)	70 to 80	70 to 78	-
Gender categorical			
Units: Subjects			
Female	44	46	90
Male	51	49	100

End points

End points reporting groups

Reporting group title	Desflurane
Reporting group description: Patients randomly assigned to desflurane received desflurane for maintenance of anesthesia after endotracheal intubation.	
Reporting group title	Sevoflurane
Reporting group description: Patients randomly assigned to sevoflurane received sevoflurane for general anesthesia after endotracheal intubation.	
Reporting group title	Sevoflurane
Reporting group description: Patients randomly assigned to sevoflurane received sevoflurane for general anesthesia.	
Reporting group title	Desflurane
Reporting group description: Patients randomly assigned to desflurane received desflurane for general anesthesia.	
Reporting group title	Desflurane
Reporting group description: Patients randomly assigned to desflurane received desflurane for maintenance of anesthesia after endotracheal intubation.	
Reporting group title	Sevoflurane
Reporting group description: Patients randomly assigned to sevoflurane received sevoflurane for general anesthesia after endotracheal intubation.	

Primary: Primary Outcome

End point title	Primary Outcome
End point description: Anesthesia recovery, which was defined as the arrival at the PACU until discharge criteria were reached (Aldrete score more than 12) for a maximum of 2 hours.	
End point type	Primary
End point timeframe: Anesthesia recovery	

End point values	Desflurane	Sevoflurane		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95 ^[1]	95 ^[2]		
Units: Duration of PACU stay				
median (inter-quartile range (Q1-Q3))	0 (0 to 0)	0 (0 to 0)		

Notes:

[1] - intention-to-treat analysis

[2] - intention-to-treat analysis

Statistical analyses

Statistical analysis title	Primary outcome
Statistical analysis description:	
For the primary outcome a Wilcoxon-signed rank test was used.	
Comparison groups	Desflurane v Sevoflurane
Number of subjects included in analysis	190
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	Median difference (final values)

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

first three postoperative days

Adverse event reporting additional description:

File with SAE was attached.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: File with SAE and publication was attached.

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/39121786>