



Clinical trial results:

The effect of pregabalin on the minimal alveolar concentration of sevoflurane

Summary

EudraCT number	2017-001439-37
Trial protocol	AT
Global end of trial date	25 February 2021

Results information

Result version number	v1 (current)
This version publication date	07 May 2023
First version publication date	07 May 2023

Trial information

Trial identification

Sponsor protocol code	MACSevoPregabalin
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Waehringer Guertel 18-20, Vienna, Austria, 1090
Public contact	Department of General Anaesthesia, Medical University of Vienna, thomas.hamp@meduniwien.ac.at
Scientific contact	Department of General Anaesthesia, Medical University of Vienna, thomas.hamp@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 February 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	25 February 2021
Global end of trial reached?	Yes
Global end of trial date	25 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study aims to investigate the effect of clinically used doses of Pregabalin on the minimum alveolar concentration of sevoflurane to provide more information to clinicians using this adjunctive drug in the perioperative setting.

Protection of trial subjects:

It was made sure that participants were thoroughly informed about trial procedures. Additionally, it was made sure that they were not part of another trial that might coincide.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 October 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects**Subjects enrolled per country**

Country: Number of subjects enrolled	Austria: 78
Worldwide total number of subjects	78
EEA total number of subjects	78

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)	78
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The operation schedule for the following day was checked and suitable patients identified. They were then asked to participate in the study, one day prior to their inclusion.

Pre-assignment

Screening details:

The patients medical files were checked to make sure they matched the inclusion criteria.

Period 1

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

Blinding implementation details:

See study protocol section 4.1

Arms

Are arms mutually exclusive?	Yes
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Arm title	Placebo
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

150mg placebo were administered at least one hour before anaesthesia orally

Arm title	Pregabalin 150mg
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Pregabalin 150mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

150mg pregabalin were administered at least one hour before anaesthesia orally

Arm title	Pregabalin 300mg
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Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Pregabalin 300mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

300mg pregabalin were administered at least one hour before anaesthesia orally

Number of subjects in period 1	Placebo	Pregabalin 150mg	Pregabalin 300mg
Started	28	25	25
Completed	25	25	25
Not completed	3	0	0
Three of these patients did not complete the study	3	-	-

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Pregabalin 150mg
Reporting group description: -	
Reporting group title	Pregabalin 300mg
Reporting group description: -	

Reporting group values	Placebo	Pregabalin 150mg	Pregabalin 300mg
Number of subjects	28	25	25
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	28	25	25
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical Units: Subjects			
Female	28	25	25
Male	0	0	0

Reporting group values	Total		
Number of subjects	78		
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)	78		
From 65-84 years	0		
85 years and over	0		
Gender categorical Units: Subjects			
Female	78		
Male	0		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Pregabalin 150mg
Reporting group description: -	
Reporting group title	Pregabalin 300mg
Reporting group description: -	

Primary: minimum alveolar concentration

End point title	minimum alveolar concentration
End point description:	
End point type	Primary
End point timeframe:	beginning until 15 minutes after beginning of anaesthesia

End point values	Placebo	Pregabalin 150mg	Pregabalin 300mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	28	25	25	
Units: procent				
median (confidence interval 95%)	1.44 (1.26 to 1.70)	1.81 (1.49 to 2.13)	2.16 (2.07 to 2.32)	

Statistical analyses

Statistical analysis title	Comparison of minimum alveolar concentrations
Statistical analysis description:	The primary endpoint was the MAC of sevoflurane in the three study groups. The MAC values of the sevoflurane concentration of the three groups were estimated using isotonic regression methods
Comparison groups	Placebo v Pregabalin 150mg v Pregabalin 300mg
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	= 0.05 ^[2]
Method	isotonic regression methods

Notes:

[1] - The primary endpoint was the MAC of sevoflurane in the three study groups. The MAC values of the sevoflurane concentration of the three groups were estimated using isotonic regression methods

[2] - not applicable

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Begin of trial till 24h after.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

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

Notes:

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

Justification: There are no adverse events in this study.

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