



Clinical trial results: The Effect of Pregabalin on the Cp50 of Propofol Summary

EudraCT number	2021-003664-28
Trial protocol	AT
Global end of trial date	20 November 2023

Results information

Result version number	v1 (current)
This version publication date	03 April 2026
First version publication date	03 April 2026

Trial information

Trial identification

Sponsor protocol code	Cp50PropofolPregabalin
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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 Anaesthesia, Medical University of Vienna, walter.ploechl@meduniwien.ac.at
Scientific contact	Department of Anaesthesia, Medical University of Vienna, walter.ploechl@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	20 November 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 November 2023
Global end of trial reached?	Yes
Global end of trial date	20 November 2023
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 a clinically used dose of Pregabalin on the Cp50 of propofol to provide more information to clinicians using this adjunctive drug in the perioperative setting.

Protection of trial subjects:

Medical insurance for trial subjects

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2022
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: 88
Worldwide total number of subjects	88
EEA total number of subjects	88

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)	88
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

We recruited only adult patients with an American Society of Anesthesiologists (ASA) physical status of I or II who were scheduled for elective surgery. For standardization, we included only female patients who underwent breast surgery. Furthermore, patients were required to be between 25 and 65 years old with a body mass index between 18.5-30

Pre-assignment

Screening details:

OR schedule was checked for eligibility

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo capsule 1-2 hours before surgery

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

Dosage and administration details:

1 capsule, 1-2 hours before surgery

Arm title	Pregabalin
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Arm description:

Pregabalin 300mg capsule 1-2 hours before surgery

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

Dosage and administration details:

300mg Pregabalin capsule 1-2 hours before surgery

Number of subjects in period 1	Placebo	Pregabalin
Started	45	43
Completed	40	40
Not completed	5	3
Organisation	5	3

Baseline characteristics

Reporting groups

Reporting group title	Placebo
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Reporting group description:

Placebo capsule 1-2 hours before surgery

Reporting group title	Pregabalin
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Reporting group description:

Pregabalin 300mg capsule 1-2 hours before surgery

Reporting group values	Placebo	Pregabalin	Total
Number of subjects	45	43	88
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)	45	43	88
From 65-84 years	0	0	0
85 years and over	0	0	0
Gender categorical			
Units: Subjects			
Female	45	43	88
Male	0	0	0

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Placebo capsule 1-2 hours before surgery	
Reporting group title	Pregabalin
Reporting group description: Pregabalin 300mg capsule 1-2 hours before surgery	
Subject analysis set title	CP50
Subject analysis set type	Per protocol
Subject analysis set description: After anesthesia induction, propofol continued to be the sole anesthetic agent and was continuously administered via a motor pump. The surgical site was then cleaned and prepared. Propofol infusion was maintained for at least 20 minutes to reach equilibrium between the effect-site and plasma. Subsequently, the surgeon made a standardized skin incision of 3 to 5 cm, depending on the exact location of the incision and type of operation. Two blinded investigators observed patients' motor responses to the skin incision for 1 minute. One investigator assessed the head and upper extremities, while the other observed the lower extremities. If either investigator reported gross purposeful movement of the head or at least one extremity within 1 minute, the motor response was classified as "positive." Coughing, bucking, and straining were not considered. If there was no movement, it was considered a negative response.	

Primary: CP50

End point title	CP50
End point description:	
End point type	Primary
End point timeframe: 20 min.	

End point values	Placebo	Pregabalin		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	43		
Units: mcg/ml				
number (confidence interval 95%)	16.9 (15.1 to 18.8)	9.4 (4.5 to 14.3)		

Statistical analyses

Statistical analysis title	CP50
Comparison groups	Placebo v Pregabalin

Number of subjects included in analysis	88
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0
Method	Logistic regression amd bootstrap

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

4 hours

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	26.1
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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: There was no adverse events

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