



Clinical trial results:

Effect of systemic antibiotic therapy on postoperative complications in patients undergoing wisdom teeth removal surgery. A double-blind, randomised, placebo-controlled Trial

Summary

EudraCT number	2017-004986-28
Trial protocol	AT
Global end of trial date	06 September 2022

Results information

Result version number	v1 (current)
This version publication date	18 August 2024
First version publication date	18 August 2024
Summary attachment (see zip file)	Clinical Oral Investigations (2022) 26:6409-6421 (784_2022_Article_4597.pdf)

Trial information

Trial identification

Sponsor protocol code	AMOXI
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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 Graz
Sponsor organisation address	Neue Stiftingtalstrasse 6, Graz, Austria, 8010
Public contact	Principal Investigator , Prof PD DDr. Michael Payer, 0043 316385 80659, mi.payer@medunigraz.at
Scientific contact	Principal Investigator , Prof PD DDr. Michael Payer, 1638578049 316385 80659, mi.payer@medunigraz.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	02 February 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 February 2022
Global end of trial reached?	Yes
Global end of trial date	06 September 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate whether the perioperative usage of antibiotics is effective in reducing postoperative complications, compared to placebo, in patients undergoing wisdom teeth removal.

Protection of trial subjects:

standard of care study

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 January 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: 59
Worldwide total number of subjects	59
EEA total number of subjects	59

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)	10
Adults (18-64 years)	49
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients aged 16 years or older who were referred for surgical removal of four impacted or slightly impacted wisdom teeth between May 2019 and July 2021 were considered participants in this study.

Period 1

Period 1 title	RCT (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
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Arm title	Amoxicillin
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Arm description: -

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

Dosage and administration details:

An hour before the start of wisdom tooth removal on the day of the first and second surgery, all patients received 40 mg of methylprednisolone orally and their study medication (26 hard gelatin capsules in a resealable container). The study medication was prepared at the local hospital pharmacy using Amoxilan 1000-mg tablets, newly packaged into hard gelatin capsules containing 250 mg amoxicillin each. Eight capsules were taken immediately, and on the following 3 days, six capsules (3 × 2 every 8 h).

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:

An hour before the start of wisdom tooth removal on the day of the first and second surgery, all patients received 40 mg of methylprednisolone orally and their study medication (26 hard gelatin capsules in a resealable container). The study medication was prepared at the local hospital pharmacy using Amoxilan 1000-mg tablets, newly packaged into hard gelatin capsules containing 250 mg amoxicillin each. Eight capsules were taken immediately, and on the following 3 days, six capsules (3 × 2 every 8 h).

Number of subjects in period 1	Amoxicillin	Placebo
Started	30	29
Completed	25	25
Not completed	5	4
Consent withdrawn by subject	5	4

Baseline characteristics

End points

End points reporting groups

Reporting group title	Amoxicillin
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Surgical site infections (SSI)

End point title	Surgical site infections (SSI)
End point description:	
End point type	Primary
End point timeframe:	
day 1 and day 7 post surgery	

End point values	Amoxicillin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	24		
Units: numbers	25	24		

Statistical analyses

Statistical analysis title	Fisher's exact test
Statistical analysis description:	
For the primary outcome variable, Fisher's exact test was performed	
Comparison groups	Amoxicillin v Placebo
Number of subjects included in analysis	49
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Fisher exact

Adverse events

Adverse events information

Timeframe for reporting adverse events:

25-Mar-2019 until 24-Mar-2022

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	adverse events
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Reporting group description: -

Serious adverse events	adverse events		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 50 (2.00%)		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 February 2019	Version 4.0, dated 28-Feb-2019

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported