



Clinical trial results:

Einfluss von peroraler Methylprednisolon-Gabe auf die postoperative Morbidität nach operativer Weisheitszahnentfernung im Unterkiefer.

(Influence of peroral Methylprednisolone administration on the postsurgical morbidity after surgical removal of lower third molars.)

Summary

EudraCT number	2007-006252-19
Trial protocol	AT
Global end of trial date	23 October 2010

Results information

Result version number	v1 (current)
This version publication date	09 December 2020
First version publication date	09 December 2020

Trial information

Trial identification

Sponsor protocol code	1.0.
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Department of Oral Surgery and Radiology,
Sponsor organisation address	Billrothgasse 4, Graz, Austria, 8010
Public contact	Clinical trials information, Department of Oral Surgery and Radiology,, norbert.jakse@medunigraz.at
Scientific contact	Clinical trials information, Department of Oral Surgery and Radiology,, norbert.jakse@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	30 October 2010
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 October 2010
Global end of trial reached?	Yes
Global end of trial date	23 October 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To find out if methylprednisolone reduces the postsurgical trismus, pain and swelling of the cheek after surgical removal of lower third molars.

Protection of trial subjects:

The study protocol and the informed consent form were approved by the Research and Ethics Committee of the Medical University Graz, Austria.

The trial adhered to Good Clinical Practice guidelines, including the Declaration of Helsinki

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 November 2008
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: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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)	16
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Sixteen patients were recruited.

The study was set up in a split-mouth design, so every patient received treatment and placebo.

Pre-assignment

Screening details:

16 patients were enrolled, there were no screening failures

Period 1

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

Arms

Arm title	Split-mouth: treatment and placebo
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Arm description:

At random, each patient received weight-dependent methylprednisolone (40–80 mg) and a placebo orally 1 hour prior to surgery.

Every patient received treatment and placebo due to the split mouth design.

Arm type	Experimental and placebo (split mouth)
Investigational medicinal product name	Methylprednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dosage was applied depending on the patients' body weight (40-80 mg).

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

At random, each patient received either weight-dependent methylprednisolone (40–80 mg) or a placebo orally 1 h prior to surgery. In each case, surgery was performed in independent visits.

Number of subjects in period 1	Split-mouth: treatment and placebo
Started	16
Completed	16

Baseline characteristics

Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	16	16	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	16	16	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	10	10	
Male	6	6	

End points

End points reporting groups

Reporting group title	Split-mouth: treatment and placebo
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Reporting group description:

At random, each patient received weight-dependent methylprednisolone (40–80 mg) and a placebo orally 1 hour prior to surgery.

Every patient received treatment and placebo due to the split mouth design.

Primary: Trismus

End point title	Trismus ^[1]
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End point description:

Data analysis revealed a significant difference between the steroid group and placebo group on the first (P00.001) and third (P00.001) post-interventional days. The restriction of the mouth opening in the steroid group (day 1, 10.3 %; day 3, 5.4 %) was less than in the placebo group (day 1, 31.3 %; day 3, 20.4 %). On the seventh day after surgery, maximal inter-incisal opening approximated the preoperative situation in both groups (P00.462).

End point type	Primary
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End point timeframe:

7 days postoperatively

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Statistical analysis is presented in the end point description due to validation problems in the system, caused by the split-mouth design of the study (16 patients were included, but in total 32 interventions- placebo and treatment per patient - were administered).

This caused validation issues in the statistical analysis section.

End point values	Split-mouth: treatment and placebo			
Subject group type	Reporting group			
Number of subjects analysed	16 ^[2]			
Units: millimeters	16			

Notes:

[2] - Since a split-mouth design was used all patients received both placebo and treatment.

Statistical analyses

No statistical analyses for this end point

Secondary: Pain

End point title	Pain
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End point description:

Throughout the whole study period, VAS pain scores of the steroid group revealed a significant lower level (P00.001) than in the placebo group. The steroid group's mean graph started and ended more than 10 mm lower than the placebo group's graph on a 100 mm scale. Both scores decreased significantly over time.

End point type	Secondary
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End point timeframe:
7 days postoperatively

End point values	Split-mouth: treatment and placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: Units on VAS score	16			

Statistical analyses

No statistical analyses for this end point

Secondary: Analgesic drug demand

End point title	Analgesic drug demand
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End point description:

For the whole study period, analgesic intake in the steroid group was significantly decreased compared with the placebo group . The mean of daily analgesic doses diminished in both groups significantly over time.

End point type	Secondary
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End point timeframe:

7 days postoperatively

End point values	Split-mouth: treatment and placebo			
Subject group type	Reporting group			
Number of subjects analysed	16			
Units: milligram	16			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From informed consent to study completion

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23,1
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Reporting groups

Reporting group title	Split-mouth: treatment and placebo
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Reporting group description:

At random, each patient received weight-dependent methylprednisolone (40–80 mg) and a placebo orally 1 hour prior to surgery.

Every patient received treatment and placebo due to the split mouth design.

Serious adverse events	Split-mouth: treatment and placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Split-mouth: treatment and placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 16 (100.00%)		
General disorders and administration site conditions			
Pain	Additional description: Postoperative pain		
subjects affected / exposed	15 / 16 (93.75%)		
occurrences (all)	31		
Swelling			
subjects affected / exposed	16 / 16 (100.00%)		
occurrences (all)	27		
Musculoskeletal and connective tissue disorders			

Trismus			
subjects affected / exposed	16 / 16 (100.00%)		
occurrences (all)	32		

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