

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparing the effect of injectable betamethasone with oral betamethasone in mandibular wisdom teeth surgery.

Protocol summary

Study aim

1.Comparison of pain intensity in surgery and extraction of wisdom tooth between injectable betamethasone group and oral betamethasone 2.Comparison of swelling intensity in surgery and extraction of wisdom tooth between injectable betamethasone group and oral betamethasone 3.Comparison of Trismus Severity in Surgery and Wisdom Tooth Extraction in Injectable Betamethasone and Oral Betamethasone

Design

The randomized double-blinded clinical trial

Settings and conduct

24 patients referred to the Tabriz dental school with the third molar in a similar situation and with the same degree of difficulty are included in the study and randomly divided into two groups of 12 people.Before having the surgery, in the first group betamethasone will be injected to the Vestbol and in second group, 2 mg oral betamethasone was taken. The severity of pain is measured 6 hours, day 1 and 3 after surgery.Trismus determined by measuring the maximum opening of the mouth and inflation is specified as tragus reference points to the corner of the lips at 48 hours and 7 days after surgery

Participants/Inclusion and exclusion criteria

Entry criteria : 1. Age limit is between 18 to 35 years old
2. The symmetric presence of impacted third molars in two directions of lower jaw
3. The difficulty level of one side surgery is equal comparing to the other side
Exit criteria: 1-Usage of drugs that can interfere the treatment process
2-Having the systemic diseases
3-Existence of perryonitis or infection or pain during operation
4-Contraindications to steroids
5-Recent use of non-steroidal inflammatory drugs
6-Pregnancy

Intervention groups

Injectable betamethasone group and oral betamethasone group

Main outcome variables

injectable betamethasone/oral betamethasone; time of

pain (Pain is measured 6,24 and 36 hours after surgery);
Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180117038415N2**

Registration date: **2018-08-31, 1397/06/09**

Registration timing: **retrospective**

Last update: **2018-08-31, 1397/06/09**

Update count: **0**

Registration date

2018-08-31, 1397/06/09

Registrant information

Name

Ali Mortazavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 5965

Email address

mortazavia@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-15, 1397/03/25

Expected recruitment end date

2018-08-16, 1397/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of injectable betamethasone with oral betamethasone in mandibular wisdom teeth surgery.

Public title

Comparing the effect of injectable betamethasone with oral betamethasone in mandibular wisdom teeth surgery.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age limit is between 18 to 35 years old The symmetric presence of impacted third molars in two directions of lower jaw The difficulty level of one side surgery is equal comparing to the other side

Exclusion criteria:

Usage of drugs that can interfere the treatment process Having the systemic diseases Existence of pericoronitis or infection or pain during operation Contraindications to steroids Recent use of non-steroidal inflammatory drugs Pregnancy

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

impacted third molar of mandible

Randomization (investigator's opinion)

Randomized

Randomization description

Referring patients to Tabriz Faculty Of Dentistry for mandibular wisdom teeth surgery from 15/06/2018 to 16/08/2018 are numbered, after observing the entry and exit requirements of the study. Then, using a random number table, we select 24 numbers from this table and enter the subject.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the participating patients and physician will be informed of the type of treatment intervention (1-Injectable betamethasone or 2-Oral betamethasone), however, the evaluator of the results will not be aware of the intervention method, so the study will be single-blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166615953

Approval date

2018-08-06, 1397/05/15

Ethics committee reference number

IR.TBZMED.REC.1397.380

Health conditions studied**1****Description of health condition studied**

Impacted wisdom teeth

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes**1****Description**

Pain intensity

Timepoint

6,24 and 36 hours after surgery

Method of measurement

Visual Analogue Scale

2**Description**

Inflation

Timepoint

48 hours , 7 days

Method of measurement

tragus reference points to the corner of the lips

3**Description**

Trismus

Timepoint

48 hours , 7 days

Method of measurement

The maximum opening of the mouth

Secondary outcomes

empty

Intervention groups**1****Description**

First intervention group: Injection of 2 mg betamethasone to the Vestbol before having the surgery

Category

Treatment - Drugs

2**Description**

Second intervention group: Consumption of 2 mg oral betamethasone before having the surgery

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, IRAN

Full name of responsible person

Ali Mortazavi

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Email

mortazavia@tbzmed.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Abolgasem Jouyban

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Golgasht Ave, Tabriz

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Ali Mortazavi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Ali Mortazavi

Position

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Latest degree

Specialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data obtained from the participants, including the pain intensity, inflation and Trismus of these individuals, can be presented in the form of a table. The protocol for the study, which is routine methods, has no problems with its publication. Statistical analysis can also be provided. In this study, an informed consent form will be used that can be published without mentioning the person's name and personal details. A clinical study report can be made after the necessary analyzes.

When the data will become available and for how long

Start the access period 9 months after publishing the results

To whom data/document is available

For researchers in Dental school of Tabriz University

Under which criteria data/document could be used

For scholars working in other academic and academic institutions, if approved by the project implementer

From where data/document is obtainable

Dr. Ali Mortazavi, email or phone Dental school of Tabriz University, Oral & Maxillofacial Surgery Department 9143175166 0098, aliweb001@gmail.com

What processes are involved for a request to access data/document

After receiving the request will be answered within a week.

Comments