

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison between the effects of dexamethasone and betamethasone on decreasing the complications after the surgical extraction of mandibular impacted third molars

Protocol summary

Summary

The aim of this clinical trial is to compare the efficacy of dexamethasone and betamethasone on reducing complications after impacted mandibular third molar surgery. Inclusion criteria includes: third mandibular molar impaction classification referred to Pell and Gregory (Class II III) and the same difficulty of the surgery on both sides. Exclusion criteria includes: systemic disease; presence of pericoronitis infection or pain before surgery; steroid contraindication and recent history of inflammatory non-steroidal drug use. Twenty adult patients of both genders who have bilateral impacted third molars with similar situations and are referred to Oral and Maxillofacial Department, will be chosen. Dexamethasone or betamethasone is injected in the vestibule at the site of surgery in the first operation. Next appointment will be held at least two weeks later, which the other drug is injected in the same manner after the surgery. Pain is assessed on 2nd and 7th day after the surgery using Visual Analog Scaling. Swelling is measured by facial reference point from tragus to the lip commissural and measurement of trismus is performed by using the inter incisor distance before, 2 and 7 days after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312093750N4**
Registration date: **2014-01-20, 1392/10/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-20, 1392/10/30

Registrant information

Name

Bahman Derakhshan

Name of organization / entity

International Campus, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-09-08, 1392/06/17

Expected recruitment end date

2013-12-08, 1392/09/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effects of dexamethasone and betamethasone on decreasing the complications after the surgical extraction of mandibular impacted third molars

Public title

Effect of dexamethasone and betamethasone on decreasing the complications after the surgical extraction of mandibular impacted third molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 15 and 30 years; Pell and Gregory classification (class II or III); Equivalent degree of surgical difficulty comparing one side with the other.

Exclusion criteria: Use of medication that could interfere with the healing process; Systemic disease; Pericoronitis, infection or pain at the time of operation;

Contraindications for using steroids; Recent history of non-steroidal anti-inflammatory drug use; pregnant woman

Age

From **15 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Both patient and the person who performs the measurements are blinded from the corticosteroid used in each surgery. None of the surgeon and the assistant will perform the assessments. The randomization of the groups is done using 4-row blocks.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

6th floor, Central University Building, Ghods Ave,
Keshavarz Blvd

City

Tehran

Postal code

Approval date

2013-09-07, 1392/06/16

Ethics committee reference number

1193/130/92/5

Health conditions studied

1

Description of health condition studied

mandibular impacted third molar

ICD-10 code

K01.1

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

2nd and 7th day after intervention

Method of measurement

Visual analogue scale

2

Description

Maximum mouth opening

Timepoint

Before and 2 and 7 days after the intervention

Method of measurement

Ruler

3

Description

Swelling

Timepoint

Before and 2 and 7 days after intervention

Method of measurement

Paper strip

Secondary outcomes

empty

Intervention groups

1

Description

Infiltrate injection of betamethasone (4 mg) corticosteroids at the buccal vestibule around the site of surgery

Category

Treatment - Drugs

2

Description

Infiltrate injection of dexamethasone (8 mg) corticosteroids at the buccal vestibule around the site of surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

International Campus, School Of Dentistry ,Tehran
University of Medical Sciences

Full name of responsible person

Dr. Bahman Derakhshan

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Sayed Jalal Pourhashemi

Street address

School of Dentistry, Mahan Blvd, Khani-Abad No

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

International Campus, School Of Dentistry ,Tehran
University of Medical Sciences

Full name of responsible person

Dr.Bahman Derakhshan

Position

Faculty member/ Assistant professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty