

# 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)

##### Phone

+98 21 5585 1149

##### Email address

dbahmand@irimc.org

#### 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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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

International Campus, School Of Dentistry ,Tehran  
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**Full name of responsible person**

Dr. Bahman Derakhshan

**Position**

Faculty member/Assistant Professor

**Other areas of specialty/work**

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**Email**

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## 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*