

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Post surgical effect of submucosal v/s intramuscular dexamethasone on pain and swelling after mandibular third molar surgery

#### Protocol summary

##### Study aim

The effectiveness of intramuscular v/s submucosal injection of dexamethasone on third molar surgery complications.

##### Design

Forty-four patients with mesioangular mandibular impacted third molar , without any specific systemic conditions, are randomly divided into 2 groups based on four random blocks.

##### Settings and conduct

This research is conducted in the department of surgery at the College of International Campus. Forty-four patients are randomly divided into two groups, and each patient is not aware of the type of injection. Then, in the course of surgery, before surgery, dexamethasone injection was performed in 2 groups (submucosal group and another intramuscular group).

##### Participants/Inclusion and exclusion criteria

The patients with mesioangular mandibular third molar in the age of 20-35 without any history of systemic disease.

##### Intervention groups

we do the injection of dexamethasone submucosally in one group and intramuscularly in the other one.

##### Main outcome variables

Decrease the pain after third molar surgery. Increase the quality of life after surgery. Decrease the swelling after third molar surgery.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180103038204N1**

Registration date: **2018-02-04, 1396/11/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-02-04, 1396/11/15**

Update count: **0**

##### Registration date

2018-02-04, 1396/11/15

##### Registrant information

###### Name

mahsa tavahodi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 4458 2706

###### Email address

mahsa.tavahodi72@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-01, 1396/09/10

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Post surgical effect of submucosal v/s intramuscular dexamethasone on pain and swelling after mandibular third molar surgery

##### Public title

Dexamethasone effect on pain and swelling

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

The patients with mesioangular mandibular third molar

surgery The patients of 20-35 years old

**Exclusion criteria:**

The patients with any systemic disease Different types of impaction except mesioangular type The patients that use any kind of medicine The patients that mention a record of allergy to dexamethasone drug The patients that cant be present at the surgery follow up

**Age**

From **20 years** old to **35 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization in groups in based on block randomization

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this project,after giving the necessary advices to the patient, they wont be aware of being in which group. The person that do the measurements in follow ups , is not aware too. Also the surgeon doesnt know the type of injection.

**Placebo**

Not used

**Assignment**

Other

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee, Vice-Chancellor for Research, Tehran University of Medical Sciences

**Street address**

keshavarz BLV.

**City**

tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2016-11-15, 1395/08/25

**Ethics committee reference number**

IR.TUMS.VCR.REC.1395.1033

**Health conditions studied**

1

**Description of health condition studied**

Mandibular impacted third molar tooth

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Reducing of pain.

**Timepoint**

Measuring the pain before surgery, on the first, third and seventh days after surgery.

**Method of measurement**

Measuring the pain using visual analogue scaling.

2

**Description**

Reducing the swelling.

**Timepoint**

Measuring the swelling before surgery, on the first, third and seventh days after surgery

**Method of measurement**

Examining the swelling by measuring facial landmarks.

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: First intervention group: 4mg of dexamethasone injected submucosally at the site of surgery 30 minutes before the start of operation.

**Category**

Treatment - Drugs

2

**Description**

Intervention group: The second intervention group injects 4 mg dexamethasone intramuscularly 30 minutes before surgery.

**Category**

Treatment - Drugs

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Tehran university-International campus of medical science

**Full name of responsible person**

Mojtaba Salehi Karizmeh

**Street address**

Khani abad, Mahan Ave., International campus of medical science

**City**

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**Email**

Mahsa.tavahodi72@yahoo.com

### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

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**Full name of responsible person**

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

No

**Title of funding source**

Financing is done by myself.

**Proportion provided by this source**

100

**Public or private sector**

Private

**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**

Tehran University of Medical Sciences

**Full name of responsible person**

Mahsa Tavahodi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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### Person responsible for updating data

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available