

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparing Pain and Swelling after Surgical Extraction of Mandibular Third Molar in Dexamethasone Injection to Medial Pterygoid and without Corticosteroid Method

#### Protocol summary

##### Summary

In some cases, impacted wisdom teeth should be extracted. Surgical extraction of these impacted third molars may provide special complication as pain, swelling, and trismus. In previous studies, some techniques as sutureless flap closure, modified flap designing, antibiotic usage, and injection of corticosteroids were presented. These methods are reducing post operative complications to moderate level. In this study, pain, swelling, trismus, general patients' satisfaction, and associated quality of life after the surgical removal of third mandibular impacted molars will be compared while injection of dexamethasone (8mg) does not need excessive time, effort, and equipments and it will be injected in numbness area into medial pterygoid muscle and pterygomandibular space to non-corticosteroid method. To achieve this aim, 60 non pregnant participants have single impacted mandibular third molar in healthy and without pericoronitis manner, after provision of written informed consent will be entered to the study. During the study, unwilling participants to continue the study and those with abnormality of wound healing process will be excluded. The included participants will be assigned into two 30-people groups. The surgeries were done by 3 same instructed experienced oral and maxillofacial residents. After the surgery pain, swelling, trismus, general patients' satisfaction, and associated quality of life were evaluated using interview of questionnaire in 48 hour, 96 hour, and one week period of time. The comparison was done between these two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013042713140N1**

Registration date: **2013-05-19, 1392/02/29**

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

Last update:

Update count: **0**

##### Registration date

2013-05-19, 1392/02/29

##### Registrant information

###### Name

Mohammadjavad Shirani

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 2422 5600

###### Email address

javaad.sh\_f@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2013-04-28, 1392/02/08

##### Expected recruitment end date

2014-06-27, 1393/04/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing Pain and Swelling after Surgical Extraction of Mandibular Third Molar in Dexamethasone Injection to

**Public title**

Comparing Pain & Swelling after Surgical Extraction of Mandibular Third Molar in Intra-oral Dexamethasone Injection and without it

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: non pregnant participants have single impacted mandibular third molar in healthy and without pericoronitis manner. They must have no contra-indication for injection of the corticosteroid and lidocaine with epinephrine and also, should not medicated by any possibly bias maker drug. Type of the impaction, must not provide sever difficulty. The participants should be mentally at healthy level and provide written informed consent to incorporate in the study. Exclusion criteria: unwilling participants to continue the study and those with abnormality of wound healing process.

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Isfahan Regional Bioethics Committee

**Street address**

University of Medical Sciences. Hezar-Jarib Ave

**City**

Isfahan

**Postal code**

81745-319

**Approval date**

2013-04-25, 1392/02/05

**Ethics committee reference number****Health conditions studied****1****Description of health condition studied**

Oral health

**ICD-10 code**

Z00-Z99

**ICD-10 code description**

Factors influencing health status and contact with health services

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

Pain

**Timepoint**

48 hours and one week after intervention

**Method of measurement**

Visual analogue scale of pain- Number of required analgesics tablets

**2****Description**

Swelling

**Timepoint**

48 hours and one week after intervention

**Method of measurement**

Questionnaire

**3****Description**

Trismus

**Timepoint**

48 hours and one week after intervention

**Method of measurement**

Maximum mouth-opening

**4****Description**

General patients' satisfaction

**Timepoint**

48 hours and one week after intervention

**Method of measurement**

Visual analogue scale for satisfaction

**5****Description**

Quality of life

**Timepoint**

96 hours and one week after intervention

**Method of measurement**

Questionnaire

## Secondary outcomes

1

### Description

Trismus

### Timepoint

During the study

### Method of measurement

Maximum mouth opening- Patients complaint

## Intervention groups

1

### Description

For the case group, after the inferior alveolar block injection and before starting the surgery, single dose of dexamethasone (8mg) will be injected into medial pterygoid and pterygomandibular space

### Category

Treatment - Drugs

2

### Description

For the control group after inferior alveolar block injection, the surgical removal of impacted third mandibular molar will be done using no corticosteroid

### Category

N/A

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Faculty of Dentistry, Isfahan University of Medical Sciences

#### Full name of responsible person

Shirani Mohammadjavad

#### Street address

Department of oral and maxillofacial surgery, Faculty of Dentistry, Isfahan University of Medical Sciences

#### City

Isfahan

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Mrs. Kobra Hossein pur

#### Street address

Department of Research and Technology, Building number4, central organ of university, Medical University of Isfahan, Iran

### City

Isfahan

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Isfahan 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

Faculty of Dentistry, Isfahan University of Medical Sciences

#### Full name of responsible person

Shirani Mohammadjavad

#### Position

Student of dentistry

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

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Oral and maxillofacial surgeon

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**Full name of responsible person**

Shirani Mohammadjavad

**Position**

Student of dentistry

**Other areas of specialty/work****Street address**

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**City**

Isfahan

**Postal code****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*