

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of the effect of local and intramuscular injection of dexamethasone on the amount of mouth opening, pain and swelling following surgical removal of impacted mandibular third molars

#### Protocol summary

##### Study aim

Comparison of the effect of local and intramuscular injection of dexamethasone on the amount of mouth opening, pain and swelling following surgical removal of impacted mandibular third molars

##### Design

In this study, 25 patients referred to dental clinics (facial and maxillofacial surgery) who have similar bilateral impacted third molar are selected. After obtaining written consent about their willingness to participate in the study, they will receive intramuscular and local dexamethasone injection and surgery will done.during and after and in next follow ups measurements will done.

##### Settings and conduct

this study will be done at OMF department of tabriz dental school.25 patients who have inclusion criteria will be selected and after obtaining consent they will receive intramuscular or local injection and surgery will done. measurements will evaluate in 1st,2nd and 7th days after surgery.

##### Participants/Inclusion and exclusion criteria

The criteria for entering the study includes the difficulty of surgical process of each side should be equal compared to the other side, the patients should have double-sided impacted third molar teeth and are similar with Paul and Gregory's classification, patient's consent for surgery.

##### Intervention groups

In these groups, intramuscular or local dexamethasone injection will perform then local anesthesia will perform. after surgical incision and bone removal third molar will extract. Then the tissue will suture with Silk suture 3 0 and the patient will discharge. Measurements will taken in the later follow ups.

##### Main outcome variables

mouth opening:swelling:pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180905040955N1**

Registration date: **2019-05-31, 1398/03/10**

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

Last update: **2019-05-31, 1398/03/10**

Update count: **0**

##### Registration date

2019-05-31, 1398/03/10

##### Registrant information

##### Name

Hamidreza Mohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3344 4598

##### Email address

hamidreza.mohammadi.pajuhan@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-22, 1397/09/01

##### Expected recruitment end date

2019-07-21, 1398/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of local and intramuscular injection of dexamethasone on the amount of mouth opening, pain and swelling following surgical removal of impacted mandibular third molars

## Public title

Comparison of the effect of local and intramuscular injection of dexamethasone on side effects following surgical removal of impacted mandibular third molars

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

difficulty of surgical process on both side of surgery should be equal patient's consent for surgery. patients should have same impacted lower third molars on both side according to Pell and Gregory category.

### Exclusion criteria:

use of drugs that interact with treatment plan systemic diseases smoking pericoronitis, infection or pain on the site of surgery contraindication for use of corticosteroids recent history of using NSAIDs patients with GI problems allergy to NSAIDs pregnancy

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 25

More than 1 sample in each individual

Number of samples in each individual: 2

-

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## 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

No 69, Mandana street, Golbad street, Tabriz

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5715938861

#### Approval date

2018-07-27, 1397/05/05

#### Ethics committee reference number

IR.TBZMED.REC.1397.475

## Health conditions studied

### 1

#### Description of health condition studied

pain, edema and trismus after impacted lower third molar surgery

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

1st day and 3rd day and 7th day after surgery

#### Method of measurement

visual analogue scale

### 2

#### Description

edema

#### Timepoint

1st day and 3rd day and 7th day after surgery

#### Method of measurement

flexible ruler

### 3

#### Description

mouth opening

#### Timepoint

1st day and 3rd day and 7th day after surgery

#### Method of measurement

flexible ruler

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: In this group, local dexamethasone injection will be performed then local anesthesia will be performed.

after surgical incision and bone removal third molar will extract. Then the tissue will suture with Silk suture 3 O and the patient will discharge. Measurements will taken in the later follow ups.

**Category**

Treatment - Surgery

**2****Description**

Intervention group: In this group, intramuscular dexamethasone injection will perform then local anesthesia will perform. after surgical incision and bone removal third molar will extract. Then the tissue will suture with Silk suture 3 O and the patient will discharge. Measurements will taken in the later follow ups.

**Category**

Treatment - Surgery

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

Tabriz dental school

**Full name of responsible person**

Saeid Nezafati

**Street address**

Taneshgah str,Tabriz

**City**

Tabriz

**Province**

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**Postal code**

5715938861

**Phone**

+98 44 3344 4598

**Email**

hamidreza.mohammadi.pajuhan@gmail.com

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Saeid Nezafati

**Street address**

Daneshgah street

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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**

1

**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**

Saeid Nezafati

**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

oral and maxillofacial surgery

**Street address**

Daneshgah street

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

Tabriz University of Medical Sciences

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Saied Nezafati  
**Position**  
professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
oral and maxillofacial surgery  
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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 decision made yet.

### 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