

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 be done. During and after and in next follow ups measurements will be 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 be done. Measurements will be evaluated 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 be performed then local anesthesia will be performed. After surgical incision and bone removal, the third molar will be extracted. Then the tissue will be sutured with Silk suture 3/0 and the patient will be discharged. Measurements will be 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 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

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

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Taneshgah str,Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

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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

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Person responsible for scientific inquiries

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Latest degree

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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 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