Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 surgury 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 surgury 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 O 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 pericronitis, infection or pain on the site of surgery contraindication for use of corticostreoids 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

Street address
Taneshgah str,Tabriz

City
Tabriz

Province
East Azarbaijan

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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Tabriz

Province
East Azarbaijan

Postal code
5715938861

Phone
+98 44 3344 4598

Email
hamidreza.mohammadi.pajuhan@gmail.com

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
Saied Nezafati

Position
professor

Latest degree
Specialist

Other areas of specialty/work
oral and maxillofacial surgery

Street address
Daneshgah street

City
Tabriz

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Email
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
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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