

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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

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Name of organization / entity

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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

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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

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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

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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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