Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Medial Pterygoid and without Corticosteroid Method

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
292037

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 reqiered 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- Patienits 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 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 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
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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 Uuniversity of Isfehan, 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
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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