Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of local dexamethasone on pain, swelling and trismus after impacted third molar extraction

Protocol summary

Study aim
The purpose of this study was to compare the effect of ibuprofen and intra-muscular injection or intra-socket placement of dexamethasone on pain, swelling and trismus after impacted third molar extraction.

Design
study group consist of patients with symptomatic mesioangular wisdom tooth and aged between 18-35 years. we have 4 group that one of them is controlled and others with parallel simple randomized clinical trial with sealed envelope and 72 patients

Settings and conduct
All surgeries was conducted in the Tehran dental clinic affiliated to Tehran University of Medical Sciences, After creating anesthesia, a triangular flap was prepared from the mesial to the distobuccal area of the wisdom tooth. and were performed by a skilled surgeon without any knowledge of the type of drug intervention. Drug intervention was done by a dentist who was informed about the plan and she was not involved in other steps of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria were individuals with painful impacted lower third molar, aged over 18, and third molar mesioangular deviation in imaging. Exclusion criteria were pregnant and lactating women, systemic diseases, analgesic and anti-inflammatory drug consumption such as NSAIDs and GCs at least one week before surgery, existing or developed infectious conditions such as abscess and surgical site infection, antibiotic use at least one week before surgery, known psychiatric disorders and surgery duration longer than 30 minutes.

Intervention groups
Group 1 received dexamethasone powder 4 mg inside the alveolar socket ; group 2 received dexamethasone 4 mg/ml in the masseter muscle through the oral mucosa; group 3 received ibuprofen 400 mg tablets one hour before surgery. A hard gelatin capsule contains starch powder 1gr, was considered as a placebo (group 4).

Main outcome variables
pain trismus swelling

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201117049418N1**
Registration date: **2020-11-20, 1399/08/30**
Registration timing: **retrospective**

Last update: **2020-11-20, 1399/08/30**
Update count: **0**
Registration date
2020-11-20, 1399/08/30

Registrant information
Name
Farshad Khosraviani
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2012-02-05, 1390/11/16
Expected recruitment end date
2012-06-23, 1391/04/03
Actual recruitment start date
2012-02-05, 1390/11/16
Actual recruitment end date
2012-06-23, 1391/04/03

Trial completion date
2012-08-01, 1391/05/11

Scientific title
Effect of local dexamethasone on pain, swelling and trismus after impacted third molar extraction

Public title
Effect of dexamethasone on tooth extraction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
individuals with painful impacted lower third molar aged over 18 and less than 35 third molar mesioangular deviation in imaging

Exclusion criteria:
pregnant and lactating women systemic diseases such as diabetes and hypertension analgesic and anti-inflammatory drug consumption such as NSAIDs and GCs at least one week before surgery existing or developed infectious conditions such as abscess and surgical site infection antibiotic use at least one week before surgery known psychiatric disorders surgery duration longer than 30 minutes.

Age
From **18 years** old to **35 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **72**
Actual sample size reached: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
simple individual randomization with sealed envelops that patient choose the envelope, there were 72 sealed envelopes that each one included group number and patient choose between envelopes and then he/she was included in one group.

Blinding (investigator's opinion)
Triple blinded

Blinding description
triple-blind randomized clinical trial study (surgeon, examiner, and statistical analyst All surgeries were performed by a skilled surgeon without any knowledge of the type of drug intervention. Drug intervention was done by a dentist who was informed about the plan and she was not involved in other steps of the study

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Institutional Research Ethics Committee School of Dentistry Trhran University of Medical Sciences

Street address
loor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town

City
tehran

Province
Tehran

Postal code
1448934368

Approval date
2012-01-12, 1390/10/22

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1390.002

Health conditions studied

1

Description of health condition studied
third molar extraction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Patient’s severity of pain was measured by Visual Analogue Scale (VAS).

Timepoint
surgery day, two days after surgery and then one week after surgery

Method of measurement
This is a 100-mm ruler, which the patient marks the pain severity on it from zero (painless) to 100 (maximum pain). After receiving training, the patients expressed their severity of pain and recorded it in terms of cm.-

2

Description
Swelling To measure swelling, the distance of tragus to the corner of the lip and tragus to gonion[

Timepoint
surgery day, two days after surgery and then one week after surgery

Method of measurement
swelling, the distance of tragus to the corner of the lip

and tragus to gonion[17] was measured by a standard cloth ruler, and these values were summed and divided by two to obtain the swelling mean in the surgery side in millimeter.-

3

Description
Trismus In order to assess the maximal mouth opening, patients opened their mouth straight so that they did not have jaw deflection, pain and discomfort
Timepoint
surgery day, two days after surgery and then one week after surgery
Method of measurement
Maximal mouth opening was recorded by measuring the distance between the incisal edges of the upper and lower central teeth using a coulisse ruler in millimeter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Group 1 received dexamethasone powder 4 mg inside the alveolar socket after washing and before flap suturing
Category
Treatment - Drugs

2

Description
Intervention group: group 2 received dexamethasone 4 mg/ml in the masseter muscle through the oral mucosa before surgery and after anasthesia
Category
Treatment - Drugs

3

Description
Intervention group: group 3 received ibuprofen 400 mg tablets one hour before surgery and every 6 hours for one day
Category
Treatment - Drugs

4

Description
Control group: Control group: A hard gelatin capsule contains starch powder 1gr, was considered as a placebo which consumed orally one hour before surgery (group 4).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran dental clinic affiliated to Tehran University of Medical Sciences
Full name of responsible person
Farshad Khosraviani
Street address
3229 1/2 S Sherbourne Dr
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran 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
Tehran University of Medical Sciences
Proportion provided by this source
100
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
Tehran University of Medical Sciences
Full name of responsible person
Farshad Khosraviani
Position
Student
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
whole data are available
When the data will become available and for how long
from now till 2 years
To whom data/document is available
researcher
Under which criteria data/document could be used
N/A
From where data/document is obtainable
Farshadkhosraviani@gmail.com
What processes are involved for a request to access data/document
proposal and aim of their request
Comments