

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name of organization / entity

Country

United States of America

Phone

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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 envelopes 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 anesthesia

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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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Person responsible for updating data

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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