

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Post surgical effect of submucosal v/s intramuscular dexamethasone on pain and swelling after mandibular third molar surgery

Protocol summary

Study aim

The effectiveness of intramuscular v/s submucosal injection of dexamethasone on third molar surgery complications.

Design

Forty-four patients with mesioangular mandibular impacted third molar , without any specific systemic conditions, are randomly divided into 2 groups based on four random blocks.

Settings and conduct

This research is conducted in the department of surgery at the College of International Campus. Forty-four patients are randomly divided into two groups, and each patient is not aware of the type of injection. Then, in the course of surgery, before surgery, dexamethasone injection was performed in 2 groups (submucosal group and another intramuscular group).

Participants/Inclusion and exclusion criteria

The patients with mesioangular mandibular third molar in the age of 20-35 without any history of systemic disease.

Intervention groups

we do the injection of dexamethasone submucosally in one group and intramuscularly in the other one.

Main outcome variables

Decrease the pain after third molar surgery. Increase the quality of life after surgery. Decrease the swelling after third molar surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038204N1**

Registration date: **2018-02-04, 1396/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-04, 1396/11/15**

Update count: **0**

Registration date

2018-02-04, 1396/11/15

Registrant information

Name

mahsa tavahodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4458 2706

Email address

mahsa.tavahodi72@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Post surgical effect of submucosal v/s intramuscular dexamethasone on pain and swelling after mandibular third molar surgery

Public title

Dexamethasone effect on pain and swelling

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The patients with mesioangular mandibular third molar

surgery The patients of 20-35 years old

Exclusion criteria:

The patients with any systemic disease Different types of impaction except mesioangular type The patients that use any kind of medicine The patients that mention a record of allergy to dexamethasone drug The patients that cant be present at the surgery follow up

Age

From **20 years** old to **35 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in groups in based on block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

In this project,after giving the necessary advices to the patient, they wont be aware of being in which group. The person that do the measurements in follow ups , is not aware too. Also the surgeon doesnt know the type of injection.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Vice-Chancellor for Research, Tehran University of Medical Sciences

Street address

keshavarz BLV.

City

tehran

Province

Tehran

Postal code

1417653761

Approval date

2016-11-15, 1395/08/25

Ethics committee reference number

IR.TUMS.VCR.REC.1395.1033

Health conditions studied

1

Description of health condition studied

Mandibular impacted third molar tooth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Reducing of pain.

Timepoint

Measuring the pain before surgery, on the first, third and seventh days after surgery.

Method of measurement

Measuring the pain using visual analogue scaling.

2

Description

Reducing the swelling.

Timepoint

Measuring the swelling before surgery, on the first, third and seventh days after surgery

Method of measurement

Examining the swelling by measuring facial landmarks.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First intervention group: 4mg of dexamethasone injected submucosally at the site of surgery 30 minutes before the start of operation.

Category

Treatment - Drugs

2

Description

Intervention group: The second intervention group injects 4 mg dexamethasone intramuscularly 30 minutes before surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran university-International campus of medical science

Full name of responsible person

Mojtaba Salehi Karizme

Street address

Khani abad, Mahan Ave., International campus of medical science

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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?**

No

Title of funding source

Financing is done by myself.

Proportion provided by this source

100

Public or private sector

Private

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

Mahsa Tavahodi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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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 more information.

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