

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of the Clinical Effect of Injectable and Topical Dexamethasone on Complications After Mandibular Third Molar Surgery- A Clinical Study

Protocol summary

Study aim

Investigating the clinical effect of injectable and local dexamethasone on the complications after surgery of the impacted third molar of the mandible.

Design

After the plan is approved by the university research council and the code of ethics is obtained, the patients who meet the conditions to participate in the study will be selected. First randomization will be done and then people will be randomly divided into 3 groups. The study will be double-blinded.

Settings and conduct

surgery will be performed by a maxillofacial surgeon. The follow-up of the patients and the recording of their complications will be done by the final year dental student

Participants/Inclusion and exclusion criteria

1. Age between 17 and 35 years 2. Having personal consent 3. Having a mesioangular 3rd molar in the mandible 4. Not using antibiotics in the last three weeks

Intervention groups

I. The first group, the group that will receive only painkiller (400 mg ibuprofen) after surgery (control group). II. The second group, the group that will receive the injectable form of dexamethasone in addition to painkillers (400 mg ibuprofen) (experimental group). III. The third group, the group that will receive the topical form of dexamethasone in addition to painkillers (400 mg ibuprofen) (experimental group).

Main outcome variables

The maximum opening of the mouth will be checked by measuring the distance between the incisal edge of the central teeth with a ruler. This measurement will be repeated before surgery, 48 hours after surgery, and 7 days after surgery. visual analogue scale (VAS) will be used to measure pain. In addition, the number of pills used is also effective in measuring the pain level of

patients. The amount of swelling will be measured clinically, from the tragus of the ear to the outer corner of the mouth on the surgical side by a tape adjusted to the natural concavity of the patient's face.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230802059009N1**

Registration date: **2023-10-26, 1402/08/04**

Registration timing: **retrospective**

Last update: **2023-10-26, 1402/08/04**

Update count: **0**

Registration date

2023-10-26, 1402/08/04

Registrant information

Name

Soheil Soltani koohbanani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3870 0528

Email address

soheil.soltani2016@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Clinical Effect of Injectable and Topical Dexamethasone on Complications After Mandibular Third Molar Surgery- A Clinical Study

Public title
Comparison of the effect of injectable and topical dexamethasone on dental surgery complications

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
age of 17 to 35 personal informed consent having mesioangular impacted 3rd molar in the mandible not having a history of antibiotic consumption over the last 3 weeks

Exclusion criteria:
systemic diseases such as diabetes or blood pressure Being allergic to dexamethasone Having pericoronitis or infection pregnancy drug consumption

Age
From **17 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random block method will be used to assign samples to groups. Blocks will be considered as 3 blocks. Group type selection for each person will be done through the following site.
www.sealedenvelope.com/simple-randomiser/v1/lists

Blinding (investigator's opinion)
Double blinded

Blinding description
The study is double-blinded, and the surgeon and the researcher will not know about the patient groups. Only one person (student) who administers anesthetic and corticosteroid injection will be aware of the group of patients. The surgeon and the person who follows up the patients and records their pain and swelling levels will not know about the patient group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Moallem avenue

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2023-03-14, 1401/12/23

Ethics committee reference number

IR.MAZUMS.REC.1401.539

Health conditions studied

1

Description of health condition studied

impacted third molars

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes

1

Description

Swelling

Timepoint

before surgery, 2 days, and 7 days after surgery

Method of measurement

The amount of swelling will be measured clinically, from the tragus of the ear to the outer corner of the mouth on the surgical side by a tape adjusted to the natural concavity of the patient's face.

2

Description

trismus

Timepoint

before surgery, 2 days, and 7 days after surgery

Method of measurement

The maximum opening of the mouth will be checked by measuring the distance between the incisal edge of the central teeth with a ruler.

3

Description

pain after wisdom tooth surgery

Timepoint

before surgery, 2 days, and 7 days after surgery

Method of measurement

visual analogue scale (VAS) will be used to measure pain. In addition, the number of pills used is also effective in measuring the pain level of patients.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: This group only receives painkillers (400 mg ibuprofen) after surgery. Patients are advised to use this painkiller every 8 hours if they feel any pain

Category

Treatment - Drugs

2

Description

Intervention group 1: In this group, after surgery, 2 ml of dexamethasone 8 mg (Daro Pasha, Tehran, Iran) will be injected into the medial pterygoid muscle with a 24-gauge syringe, and ibuprofen 400 mg will be prescribed.

Category

Treatment - Drugs

3

Description

Intervention group 2: In this group, after the surgery, 10 mg of dexamethasone sodium phosphate powder (Daro Pasha, Tehran, Iran) will be gradually placed in the socket of the extracted tooth, and 400 mg ibuprofen pain reliever will also be prescribed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

tooba dental clinic

Full name of responsible person

Dr. Amirhossein Pakravan

Street address

moallem avenue

City

sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Phone

+98 11 3304 4000

Email

soheil.soltani2016@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Amirhossein Pakravan

Street address

Moallem avenue

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Phone

+98 11 3304 4000

Email

soheil.soltani2016@yahoo.com

Grant name

Research Deputy of Mazandaran University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Soheil Soltani

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Moallem avenue

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Phone

+98 11 3304 4000

Email

soheil.soltani2016@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Amirhossein Moaddabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Moallem avenue

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Phone

+98 11 3304 4000

Email

a.moaddabi2@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Soheil Soltani

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Moallem avenue

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Phone

+98 11 3304 4000

Email

soheil.soltani2016@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available