Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Study of the effect of submucosal and intramuscular injection of dexamethasone before and after mandibular impacted wisdom tooth surgery in reducing postoperative swelling and trismus

Protocol summary

Study aim

Study of the effect of submucosal and intramuscular injection of dexamethasone before and after mandibular impacted wisdom tooth surgery in reducing postoperative swelling and trismus

Design

Clinical trial without control group, with parallel groups, one-way blind, randomized, phase 2 on 72 patients. For randomization, patients were randomly assigned to a list. In this way, numbers with a four-point interval starting from 1 in group A, numbers with a four-point interval starting from 2 in group B, numbers with a four-point interval starting from 3 in group C, and numbers with a four-point interval starting from 4 in group D are divided.

Settings and conduct

The place is Arak Dental Faculty. All surgeries are performed by an experienced surgeon with the same technique. All patients receive 500 mg amoxicillin, 400 mg ibuprofen, and chlorhexidine mouthwash after surgery. All surgeries are performed by a surgeon, and in each surgery the type of flap created is triangular.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with mandibular occult wisdom teeth who do not have pericoronitis. Patients who do not have a local infection. Patients over 18 years of age. Patients who are not taking antibiotics or anti-inflammatory drugs. Patients who do not have systemic problems and allergies. Exclusion criteria: Pregnant people. People with allergies to the drugs used in the study. Patients with local infection. Patients taking antibiotics or anti inflammatory drugs. Patients with systemic problems and allergies. Patients with pericoronitis.

Intervention groups

4 groups. Group A receives 4 mg pre-operative intramuscular dexamethasone, group B receives 4 mg post-operative intramuscular dexamethasone, group C receives 4 mg pre-operative submucosal dexamethasone and group D receives 4 mg post-operative submucosal dexamethasone.

Main outcome variables

Swelling ; Trismus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211028052898N1**
Registration date: **2021-11-20, 1400/08/29**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-20, 1400/08/29**
Update count: **0**

Registration date

2021-11-20, 1400/08/29

Registrant information

Name

Mehdi Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3325 4104

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-02, 1400/08/11

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the effect of submucosal and intramuscular injection of dexamethasone before and after mandibular impacted wisdom tooth surgery in reducing postoperative swelling and trismus

Public title
Study of the effect of submucosal and intramuscular injection of dexamethasone before and after mandibular impacted wisdom tooth surgery in reducing postoperative swelling and trismus
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with impacted mandibular wisdom teeth who do not have pericoronitis. Patients with impacted mandibular wisdom teeth who do not have a local infection. Patients with impacted mandibular wisdom teeth over 18 years of age. Patients with impacted mandibular wisdom teeth who are not taking antibiotics or anti-inflammatory drugs. Patients with impacted mandibular wisdom teeth who do not have systemic problems and allergies.
Exclusion criteria:
Pregnant people. People with allergies to the drugs used in the study. Patients with local infection. Patients taking antibiotics or anti-inflammatory drugs. Patients with systemic problems and allergies. Patients with pericoronitis.
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
2
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling method is regular random, by random numbers. That is, after examination and approval of patients by a specialist on panoramic graphics, patients were randomly placed in a list of 72 people in order of inclusion in the study. Quadratic numbers starting with 1 in group A, numbers with quadratic interval starting from 2 in group B, numbers with quadratic interval starting from 3 in group C and numbers with quadratic interval starting from 4 in group D, are divided.
Blinding (investigator's opinion)
Single blinded
Blinding description
Only the surgeon, who is injecting the anesthetic and corticosteroids, is aware of the groups of patients. The student who records the level of swelling and trismus of patients is not aware of the patient group and therefore the study is one-sided blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
13th floor, Block A, Treatment and Medical Education, Central Headquarters of the Ministry of Health, between South Flamek and Zarafshan, Iran TV St, Ghods Town (West), Tehran
City
Tehran
Province
Tehran
Postal code
ethics@behdasht.gov.
Approval date
2021-11-02, 1400/08/11
Ethics committee reference number
IR.ARAKMU.REC.1400.178

Health conditions studied

1

Description of health condition studied
Swelling and trismus after impacted mandibular wisdom tooth surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Trismus after impacted mandibular wisdom tooth surgery
Timepoint
At the beginning of the study (before the intervention) and 72 hours after the intervention
Method of measurement
Measurement of the boundary line between the incisive edge of the upper and lower incisors at maximum mouth

opening by a calibrated ruler

2

Description
Swelling after mandibular wisdom tooth surgery
Timepoint
At the beginning of the study (before the intervention) and 72 hours after the intervention
Method of measurement
Using a tape measure, the distance between the earlobe to the corner of the mouth (Method A) and the inner corner of the eye to the mandibular angle (Method B)

Secondary outcomes

empty

Intervention groups

1

Description
Patients are 18 to 35 years old. All patients have third mandibular molar surgery in hard tissue. In 4 groups, inferior alveolar nerve and long buccal nerve block is performed with lidocaine. All surgeries are performed by an experienced surgeon with the same technique. Alborz Daroo is the commercial company that produces all dexamethasone. All patients receive 500 mg amoxicillin, 400 mg ibuprofen, and chlorhexidine mouthwash after surgery. All surgeries are performed by a surgeon, and in each surgery the type of flap created is triangular. Intervention group 1: receives 4 mg of intramuscular dexamethasone before surgery.
Category
Prevention

2

Description
Intervention group 2: receives 4 mg of intramuscular dexamethasone after surgery.
Category
Prevention

3

Description
Intervention group 3: receives 4 mg of submucosal dexamethasone before surgery.
Category
Prevention

4

Description
Intervention group 4: receives 4 mg of submucosal dexamethasone after surgery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Dental Faculty
Full name of responsible person
Mehdi Heydarizade
Street address
Navab Safavi Boulevard in front of the Post Office, Hepco Street
City
Arak
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Arak University of Medical Sciences - Basij Square - Arak
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Markazi
Postal code
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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
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Mehdi Heydarizade

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Maxillofacial surgery

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Position
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Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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No. 6941, Second Alley (Shahid Heydari), Besat Town Phase One

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Arak

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3817696941

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
Only part of the data, such as the original outcome information, can be shared.

When the data will become available and for how long
The access period starts one year after the results are published.

To whom data/document is available
The data will be available to all researchers.

Under which criteria data/document could be used
Any kind of analysis on the delivered data is allowed.

From where data/document is obtainable
Mehdi Ebrahimi, 09015954041, ebrahimimehdi96@gmail.com

What processes are involved for a request to access data/document
After submitting the application to the mentioned e-mail address, the documents will be sent to the applicant within one week.

Comments