

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of efficacy of pre-operative dexamethasone injection into masseter muscle versus gluteus major muscle on reducing complications due to impacted mandibular third molar surgery

Protocol summary

Study aim

Comparison of efficacy of pre-operative dexamethasone injection into masseter muscle versus gluteus major muscle on reducing complications due to impacted mandibular third molar surgery

Design

Randomized clinical trial by lottery with parallel groups, phase 3. one blind side. The sample size is 22, and a total of 44 surgical procedures

Settings and conduct

Surgery will be done on patients referred to the dental clinic of North Khorasan University of Medical Sciences and a private office. the injection site and the surgery side will be characterized by lottery. Injection of dexamethasone into the Masseter will be done after the alveolar nerve block and 1-2 hours before the surgery & the surgery on the other side will be done with a month interval & Dexamethasone injection into the gluteus 1-2 hours before surgery. Pain measurement will be done by VAS (visual analogue scale) that numbered from zero to ten, and number of consumer analgesic tablets. Edema measurement will be done by facial landmarks & trismus measurement will be done by measure the distance between the incisal edge of the upper and lower anterior teeth.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients who have impacted mandibular third molars with same difficulty, without pericoronitis and infection. Non-entry criteria include pregnant people, people who have uncontrolled systemic disease, sensitivity to dexamethasone, use of drugs that interfere with dexamethasone.

Intervention groups

Each person takes dexamethasone in the masseter muscle before the surgery on one side and in the gluteus muscle for the other side. In fact each person is his own control.

Main outcome variables

Swelling; Pain; Trismus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181204041849N1**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

Registration date

2019-02-10, 1397/11/21

Registrant information

Name

Sepideh Etemadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3624 5629

Email address

s.etemadzadeh@nkums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-01, 1397/10/11

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparison of efficacy of pre-operative dexamethasone injection into masseter muscle versus gluteus major muscle on reducing complications due to impacted mandibular third molar surgery

Public title
Effect of dexamethasone injection on reducing complications due to impacted wisdom tooth surgery

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
People who have impacted mandibular wisdom tooth in both sides with same difficulty. People who don't have pericoronitis & infection.

Exclusion criteria:
Pregnant women People who have uncontrolled systemic disease. People who have sensitivity to the drugs that are being used in the study. Use of drugs that interfere with dexamethasone.

Age
From **15 years** old to **35 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **22**
More than 1 sample in each individual
Number of samples in each individual: **2**
Impacted mandibular wisdom teeth with same difficulty

Randomization (investigator's opinion)
Randomized

Randomization description
Individual randomization will be done through lottery. On paper sheets with same color and concealed content, numbers from 0 through 9 will be put and for every patient who is studied, a number will be drawn to determine on which muscle and which side the first injection must be done. For even numbers, the injection is performed on Masseter, conversely, in case of odd numbers the patient will be injected in Gluteus. To decide on which side the surgery must be done, on two same-colored sheets of paper the words "left" and "right" will be put then a one paper is drawn. To equalize the groups in size, there will be no more draws after the quorum for subject who have been given the first injection on the same muscle is present and the rest will be injected in the other muscle at first; in other words, 11 subjects will take the first injection in Masseter and the other 11 will get the initial injection in Gluteus. furthermore, 11 patients will undergo surgery on their right side at first, whereas, the other 11 will be operated on their left side at first.

Blinding (investigator's opinion)

Single blinded

Blinding description

Information will be provided to the analyzer in the form of muscle numbers 1 & 2

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National committee of North Khorasan University of Medical Sciences

Street address

Shahriar Ave., North Khorasan University of Medical Sciences

City

Bojnord

Province

North Khorasan

Postal code

74877-94149

Approval date

2018-12-03, 1397/09/12

Ethics committee reference number

IR.NKUMS.REC.1397.056

Health conditions studied

1

Description of health condition studied

Impacted mandibular third molar surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Edema

Timepoint

Before the surgery, second & seventh day after surgery

Method of measurement

Swelling will be measured by a flexible ruler & the distance between the facial landmarks (tragus-pogonium, tragus-commissur of the lip, angle of mandible-outer canthus of eye) in millimeters.

2

Description

Pain

Timepoint

Surgical day, Day 1, Day 3 and Seventh day after surgery

Method of measurement

Patients score 10-0 according to the Standard Visual Analog Scale.

3

Description

Trismus

Timepoint

Before the surgery, second & seventh day after surgery

Method of measurement

Measure the distance between the edges of the upper and lower central incisors by a graded ruler, when the patient opens the mouth to the extent possible.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: injection of Dexamethasone 8 mg into the Masseter muscle 1-2 hours before surgery & after inferior alveolar nerve block injection for one side surgery.

Category

Prevention

2

Description

Intervention group: injection of Dexamethasone 8mg into the gluteus major muscle 1-2 hours before surgery for the other side of the same person.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental clinic of North Khorasan University of Medical Sciences

Full name of responsible person

Ali Aghai Meybodi

Street address

Shahriar Ave.; North Khorasan University of Medical Sciences

City

Bojnord

Province

North Khorasan

Postal code

9417694735

Phone

+98 58 3229 6764

Email

Ali.aghaimybodi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd University of Medical Sciences

Full name of responsible person

Seyyed Kaveh Hojjat

Street address

North Khorasan University of Medical Sciences, Shahriar st, Bojnord

City

Bojnord

Province

North Khorasan

Postal code

9417694735

Phone

+98 58 3229 6764

Email

S.Kavehhojjat1@gmail.com

Grant name

Grant code / Reference number

97/43/1324

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

Yes

Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

Full name of responsible person

Sepideh Etemadzadeh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Shahriar St., North Khorasan University of Medical Sciences

City

Bojnord

Province

North Khorasan

Postal code

9417694735

Phone

+98 58 3624 5629

Fax**Email**

s.etemadzade@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

Full name of responsible person

Sepideh Etemadzadeh

Position

Student

Latest degree

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Phone

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Fax**Email**

s.etemadzade@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Bojnourd University of Medical Sciences

Full name of responsible person

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Fax**Email**

s.etemadzade@gmail.com

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

Information about the main consequence, have the ability to share, after unidentifiable people.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers working in academic & scientific institutions

Under which criteria data/document could be used

The use of data in order to complete scientific information and research is permissible and sending a request for access to data has not a specific condition.

From where data/document is obtainable

1. North Khorasan University of Medical Sciences, dental College 2. s.etemadzade@gmail.com

What processes are involved for a request to access data/document

After sending the email, it will be answered for a few days.

Comments