Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 commitee 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.aghaimeybodi@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
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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

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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
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