

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effectiveness of Betamethasone LA injection into the masseter and medial pterygoid muscles in preventing the post-operative complications after mandibular third molar surgery

Protocol summary

Study aim

Comparison of the effectiveness of Betamethasone LA injection into the masseter and medial pterygoid muscles in preventing the post-operative complications after mandibular third molar surgery

Design

randomized single blinded Clinical trial, on 90 patients. Randomisation was done by generating random numbers using Excel software

Settings and conduct

Patients in need of mandibular third molar surgery are randomly divided into 2 groups with equal numbers. In each group, the anesthesia process will be done with the same protocol using Persocaine-E. Then 1mL ampoule of Betamethasone LA is injected into the masseter or internal pterygoid muscle. The surgery is done by the same surgeon using the standard method according to the type of impaction in the dental clinic. After that, patients are given analgesics (acetaminophen 325mg) and antibiotics (amoxicillin 500mg and metronidazole 250mg, number: 20, one every 8 hours) in the same way. Outcome assessment is done before surgery, 2 and 7 days after surgery. Patients and outcome assessors are blind in this study.

Participants/Inclusion and exclusion criteria

Inclusion: 1-ASA I or II 2-presence of a confirmed impacted mandibular third molar with no infection and pericoronitis 3- patient is ready to sign the testimonial. Exclusion: 1-History of underlying diseases 2-current consumption of drugs, alcohol, opioids 3-smoking 4-recent consumption of anti-inflammatory drugs and antibiotics 5-pregnant women 6- any allergies

Intervention groups

injection of 1mL ampoule of Betamethasone LA into the internal pterygoid muscle immediately after anesthesia . group 2: injection of 1mL ampoule of Betamethasone LA

into the masseter muscle immediately after anesthesia.

Main outcome variables

severity of pain, swelling, Paresthesia, General satisfaction, Trismus, Maximum opening of mouth, surgery difficulty level, number of analgesics taken

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191127045516N5**

Registration date: **2021-10-11, 1400/07/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-11, 1400/07/19**

Update count: **0**

Registration date

2021-10-11, 1400/07/19

Registrant information

Name

hamed Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-09, 1400/07/17

Expected recruitment end date

2021-12-08, 1400/09/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Betamethasone LA injection into the masseter and medial pterygoid muscles in preventing the post-operative complications after mandibular third molar surgery

Public title

Comparison of the effectiveness of Betamethasone LA injection into the masseter and medial pterygoid muscles in preventing the post-operative complications after mandibular third molar surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

ASA I or II health status. presence of a impacted mandibular third molar confirmed by a panoramic image absence of the mandibular third molar infection and pericoronitis The patient is ready to take part in the study and sign the testimonial

Exclusion criteria:

History of underlying diseases affecting the wound healing process like systemic diseases(diabetes,high blood pressure,gastrointestinal system diseases,kidney disorders,heart and lung diseases) current consumption of drugs,alcohol,opiums(consumption of any of these substances during the last month) smoking(someone who has smoked at least two cigarettes a day during the last month) recent consumption of anti- inflammatory drugs and antibiotics pregnant women any allergies or Hypersensitivities to the drugs used in this study

AgeFrom **18 years** old to **40 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample sizeTarget sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

Random numbers are generated using Excel software by a statistician to do this. Four-digit codes are generated. A four digit code is allocated to each patient and the last digit on the right indicates the patient group.if the number obtained is odd(1,3,5,7,9),the patient is in the internal pterygoid muscle injection group and if the number is even(0,2,4,6,8),the patient is in the masseter muscle injection group Each of the generated codes is kept separately inside the envelope and the receptionist gives one of these envelopes to the patient before

entering the doctor's room. Accordingly, the next patient code is not predictable. Based on the patient's code, the physician determines which treatments to implement, Only the physician who implements the intervention knows the code allocated to the patient, which after evaluating the outcome, based on the patient's name, the information collected will be related to the assigned codes.

Blinding (investigator's opinion)

Single blinded

Blinding description

As the injection is done in each masseter and internal pterygoid muscle its not possible to blind the patient. but the person who is in charge of assessing the outcome , is uninformed about the method of allocation of patients to groups . Therefore only outcome assessor is blinded in this study

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name****Secondary trial Id****Registration date**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

کمیته اخلاق دانشگاه علوم پزشکی کرمانشاه

Street address

Ethics Committee, Department of Research and Technology, Central Building, Shahid Beheshti Boulevard, Kermanshah

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Province

Kermanshah

Postal code

6715847141

Approval date

2021-09-11, 1400/06/20

Ethics committee reference number

IR.KUMS.REC.1400.322

Health conditions studied**1****Description of health condition studied**

severity of pain

ICD-10 code

G89.1
ICD-10 code description
Acute pain, not elsewhere classified

2

Description of health condition studied
Trismus

ICD-10 code
G71.8

ICD-10 code description
Other primary disorders of muscles

3

Description of health condition studied
swelling

ICD-10 code
R22.9

ICD-10 code description
Localized swelling, mass and lump, unspecified

4

Description of health condition studied
paresthesia

ICD-10 code
R20

ICD-10 code description
Disturbances of skin sensation

Primary outcomes

1

Description
severity of pain

Timepoint
before surgery, 2 and 7 days later

Method of measurement
Visual Analogue Scale(VAS)

2

Description
swelling

Timepoint
2 and 7 days after surgery

Method of measurement
Visual Analogue Scale(VAS)

3

Description
General satisfaction

Timepoint
2 and 7 days after surgery

Method of measurement
Visual Analogue Scale(VAS)

4

Description

Trismus

Timepoint
2 and 7 days after surgery

Method of measurement
Restrictions on opening the mouth(mild, moderate, severe)

5

Description
paresthesia

Timepoint
2 and 7 days after surgery

Method of measurement
yes/no

6

Description
Maximum opening of the mouth

Timepoint
before surgery, 2 and 7 days later

Method of measurement
by a ruler(0-50 millimetre)

7

Description
difficulty of the surgery

Timepoint
Before surgery

Method of measurement
according to panoramic radiograph based on spatial direction, depth and ramus relationship(easy, moderate, difficult)

Secondary outcomes

1

Description
Number of analgesics taken

Timepoint
2 and 7 days after surgery

Method of measurement
number(0-100)

Intervention groups

1

Description
Intervention group:1: injection of 1mL ampoule of Betamethasone LA in to the internal pterygoid muscle immediately after anesthesia injection.

Category
Prevention

2

Description
Intervention group 2: injection of 1mL ampoule of

Betamethasone LA in to the masseter muscle immediately after anesthesia injection.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

مطب دندانپزشکی دکتر نظری

Full name of responsible person

حامد نظری

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Reza Khodarahmi

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Vice Chancellor for Research and Technology,
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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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Hamed Nazari

Position

استادیار

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Position

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

مرضيه طولابی

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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