

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

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

Design

randomized double blinded Clinical trial, parallel groups, phase 2 on 84 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 30 mg ampoule of Ketorolac Trometamine 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 325 mg) and antibiotics (amoxicillin 500 mg and metronidazole 250 mg, 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

group 1: injection of 30 mg ampoule of Ketorolac Trometamine into the masseter muscle immediately after anesthesia. group 2: injection of 30 mg ampoule of

Ketorolac Trometamine into the internal pterygoid 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: **IRCT20191127045516N2**

Registration date: **2020-12-15, 1399/09/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-15, 1399/09/25**

Update count: **0**

Registration date

2020-12-15, 1399/09/25

Registrant information

Name

hamed Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 83 3835 2842

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

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

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

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the random allocation law,Random numbers are generated using Excel software by a statistician.to do this,three-digit codes are generated 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.

Blinding (investigator's opinion)

Double blinded

Blinding description

participants and outcome assessor are blinded in this study.as the ketorolac injection is done after the anesthesia,patient will not know the exact location of the injection(masseter or internal pterygoid muscle)and will not be informed.also the outcome assessor will not be informed which muscle was injected.

Placebo

Not used

Assignment

Parallel

Other design features

patients who have bilateral surgery have at least 15-days interval between each surgery and are admitted to study for only one surgery.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

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

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-09-12, 1399/06/22

Ethics committee reference number

IR.KUMS.REC.1399.607

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

Number of analgesics taken

Timepoint

2 and 7 days after surgery

Method of measurement

number(0-100)

8

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

empty

Intervention groups

1

Description

Intervention group 1: injection of 30 mg ampoule of Ketorolac Tromethamine in to the masseter muscle immediately after anesthesia injection.

Category

Prevention

2

Description

Intervention group 2: injection of 30 mg ampoule of Ketorolac Tromethamine in to the internal pterygoid muscle immediately after anesthesia injection.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Nazari Dental clinic

Full name of responsible person

Hamed Nazari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

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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

Hadis Yari

Position

Under graduated student of Dentistry

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Latest degree

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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