

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of 0.5% metronidazole rinsing solution on the edema and trismus after surgical removal of impacted mandibular third molars: randomised clinical trial

Protocol summary

Study aim

Effect of 0.5% metronidazole rinsing solution on the edema and trismus after surgical removal of impacted mandibular third molars: randomised clinical trial

Design

Clinical trials with parallel groups, single-blind, randomized. Sixty two patients will be randomly divided into two groups using Excel software.

Settings and conduct

The study will be conducted on patients referred for wisdom tooth surgery to the Department of Maxillofacial Surgery, Faculty of Dentistry, Islamic Azad University, Tehran. Sampling will be done randomly, with 31 samples for each treatment group, for a total of 62 samples. The person assessing the outcome of this study will be blinded (single-blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged between 18 and 35 years With impacted or semi-impacted maxillary and mandibular third molars classified as Class I, Level A, B, or C according to the Pell & Gregory classification Who require surgical extraction of the tooth Have acceptable oral hygiene, and Open their mouth normally Exclusion criteria: Patients with abscess Patients with cellulitis Patients with pericoronitis Patients with xerostomia Antibiotic use , Postoperative infection, History of radiotherapy Pregnancy or lactation, Allergy to metronidazole Systemic diseases (such as diabetes) Patients with cancers Smoking

Intervention groups

Intervention group: On the intervention side, the surgical area of the mandibular third molar will be rinsed with 0.5% metronidazole solution. Control group: On the intervention side, the surgical area of the mandibular third molar will be rinsed with 0.9% normal saline solution.

Main outcome variables

Clinical parameters to be assessed include: edema and trismus before surgery and at 24 hours, 3 days, 1 week, and 2 weeks after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250407065244N1**

Registration date: **2025-06-29, 1404/04/08**

Registration timing: **prospective**

Last update: **2025-06-29, 1404/04/08**

Update count: **0**

Registration date

2025-06-29, 1404/04/08

Registrant information

Name

Nariman Motahari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 902 679 1113

Email address

narimanmotahari@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-01, 1404/04/10

Expected recruitment end date

2025-09-06, 1404/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of 0.5% metronidazole rinsing solution on the edema and trismus after surgical removal of impacted mandibular third molars: randomised clinical trial

Public title

Effect of 0.5% metronidazole rinsing solution on the edema and trismus

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Aged between 18 and 35 years With impacted or semi-impacted maxillary and mandibular third molars classified as Class I, Level A, B, or C according to the Pell & Gregory classification Who require surgical extraction of the tooth Have acceptable oral hygiene, and Open their mouth normally Signing the consent form

Exclusion criteria:

Patients with abscess Patients with cellulitis Patients with pericoronitis Patients with xerostomia Aantibiotic use , Postoperative infection, History of radiotherapy Pregnancy or lactation, Allergy to metronidazole Systemic diseases (such as diabetes) Patients with cancers Smoking

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Using Excel software, patients will be randomly assigned into two groups based on the type of treatment received.

Blinding (investigator's opinion)

Single blinded

Blinding description

The outcome assessor will be unaware of the type of intervention performed, and the study will be conducted as a single-blind trial.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of the Faculty of Dentistry – Islamic Azad University, Tehran Medical Sciences Bran

Street address

Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2025-01-04, 1403/10/15

Ethics committee reference number

IR.IAU.DENTAL.REC.1403.173

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

Edema

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Trismus

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Edema

Timepoint

Prior to the surgery and 24 hours, 3 days, 1 week and 2 weeks after surgery

Method of measurement

The linear distances areas will be measured: 1 - distance from the tragus to the corner of the mouth; 2 - distance from the lateral canthus ofthe eye to the angle of the mandible; 3 - distance from the tragus to the soft tissue pogonion using ruler on the side of the surgery.

2**Description**

Trismus

Timepoint

Prior to the surgery and 24 hours, 3 days, 1 week and 2 weeks after surgery

Method of measurement

The distance between the incisal distance of central

incisor in left and right side will be measured using digital caliper.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: On the intervention side, the surgical area of the mandibular third molar will be rinsed with a 0.5% metronidazole solution.

Category

Treatment - Drugs

2

Description

Control group: On the intervention side, the surgical area of the mandibular third molar will be rinsed with 0.9% normal saline solution.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Maxillofacial Surgery, Faculty of Dentistry, Islamic Azad University, Tehran

Full name of responsible person

Dr. Hasan Mesgari

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Pasdarsn Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Dr. Hassan Mesgari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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

Islamic Azad University

Full name of responsible person

Nariman Motahari

Position

Dental Student

Latest degree

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Other areas of specialty/work

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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