Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Aantibiotic 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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Sponsors / Funding sources

1

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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

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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