

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 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

##### Street address

Pasdarsn Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1946853314

##### Phone

+98 21 2256 4571

##### Email

kmesgari@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Dr. Hassan Mesgari

##### Street address

Pasdaran Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1946853314

##### Phone

+98 21 2256 4571

##### Email

kmesgari@gmail.com

#### 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

Dentistry

##### Street address

Pasdaran Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1946853314

##### Phone

+98 21 2256 4571

##### Email

kmesgari@gmail.com

## Person responsible for scientific 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**

Dentistry

**Street address**

Pasdaran Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Email**

kmesgari@gmail.com

**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**

Bachelor

**Other areas of specialty/work**

Dentistry

**Street address**

Pasdaran Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Email**

Narimanmotahari@gmail.com

**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