

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of postoperative low-level laser therapy on pain, edema, and trismus after impacted mandibular third molar surgery: a randomized clinical trial

Protocol summary

Study aim

Clinical study of the effect of low-power diode laser application on pain, swelling and trismus after surgery for extraction of impacted mandibular third molars

Design

Photobiomodulation sessions will be performed for one week (days zero and one) and at specified intervals. The control group will receive standard postoperative treatment (such as anti-inflammatory drugs and analgesics).

Settings and conduct

The study is conducted in the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Mazandaran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Having at least one impacted lower wisdom tooth
Needing lower wisdom tooth surgery
Written consent to participate in the study
Presence of systemic and underlying diseases
Pregnancy or lactation
Unusual complications during surgery (such as jaw bone fracture, jaw dislocation, etc.)
Use of anti-inflammatory drugs or strong analgesics

Intervention groups

For the intervention group, low-power laser with a specific wavelength (970 nm) and standard settings (power 200 mW) will be used after surgery.

Main outcome variables

Pain: Will be assessed using a scale (VAS) at specific intervals after surgery. Swelling: Will be assessed by measuring specific distances on the face (such as the distance from the angle of the jaw to the apex of the zygomatic bone). Trismus: Will be assessed by measuring the distance between the upper and lower incisors with the mouth open as much as possible.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241104063590N1**

Registration date: **2025-02-24, 1403/12/06**

Registration timing: **prospective**

Last update: **2025-02-24, 1403/12/06**

Update count: **0**

Registration date

2025-02-24, 1403/12/06

Registrant information

Name

Mehdi Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3354 3852

Email address

mehdi_hashemi@sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-30, 1404/01/10

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of postoperative low-level laser therapy on pain, edema, and trismus after impacted mandibular third molar surgery: a randomized clinical trial

Public title

Effect of postoperative low-level laser therapy on pain, edema, and trismus after impacted mandibular third molar surgery: a randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having at least one impacted lower wisdom tooth
Need for lower wisdom tooth surgery
Written consent to participate in the study

Exclusion criteria:

Presence of systemic and underlying diseases
Pregnancy or breastfeeding
Unusual complications during surgery (such as jaw bone fracture, jaw dislocation, etc.)
Using anti-inflammatory drugs or strong painkillers

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients undergoing mandibular wisdom tooth extraction surgery are randomly assigned to one of two intervention or control groups by coin tossing. Randomization is done in a simple and individual manner. Randomization is done for each patient individually and without regard to the randomization results of other patients.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The laser will be used for all patients, but the laser will be turned off for the control group, so the patients will be blinded. The study investigator will not know the outcome of each patient's assignment to each group. The outcome assessor who measures the study tests will not know the outcome of each patient's randomization. The safety and data monitoring committee will not know the outcome of each patient's assignment to each group. The data analyst will not know the outcome of each patient's assignment to each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Mazandaran University of Medical Sciences and Health Services

Street address

Deputy for Research and Technology Building, Moallem Square

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2024-10-21, 1403/07/30

Ethics committee reference number

IR.MAZUMS.REC.1403.271

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52

ICD-10 code description

pain not referable to any one organ or body region

2

Description of health condition studied

trismus

ICD-10 code

R25.2

ICD-10 code description

Cramp and spasm

Primary outcomes

1

Description

Pain

Timepoint

Day of surgery - One day after surgery - One week after surgery

Method of measurement

It will be assessed using a scale (VAS) at specific intervals after surgery.

2

Description

Trismus

Timepoint

Day of surgery - One day after surgery - One week after surgery

Method of measurement

It will be assessed by measuring specific distances on the face (such as the distance from the angle of the jaw to the peak of the zygomatic bone).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, a low-power laser with a specific wavelength (970 nm) and standard settings (power 200 mW) will be used after surgery. Photobiomodulation sessions will be performed for one week (day zero and one) and at specific intervals. The laser used is a Dentsply low-power laser device made in the United States.

Category

Treatment - Devices

2

Description

Control group: The control group will receive standard postoperative treatment (such as anti-inflammatory drugs and painkillers). Acetaminophen 500 mg every 6 hours and amoxicillin every 8 hours for 5 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Mazandaran University of Medical

Full name of responsible person

Seyed Mehdi Hashemi sheykhAbadi

Street address

Faculty of Dentistry, Baghban Complex (next to Tooba Medical Complex), Khazar Boulevard, Sari, Iran

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dentistryfaculty@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

ahmad ali enayati

Street address

Deputy for Research and Technology Building, Moallem Square, Sari

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4817844718

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pajhooeshi@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

seyed mehdi hashemi sheykhAbadi

Position

Research Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

Access period starts 12 months after results are published.

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Only statistical analyses are permitted to verify the validity of the study conducted.

From where data/document is obtainable

Applicants can send their request for access to data via email to mehdi_hashemi@sbm.ac.ir.

What processes are involved for a request to access data/document

After receiving the request, the research team and study authors will review it and a response will be provided within one week.

Comments