Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 11 3354 3852

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mehdi_hashemi@sbmu.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
City
Sari
Province
Mazandaran
Postal code
4816895475
Phone
+98 11 3340 5474
Email
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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sari
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4817844718
Phone
+98 11 3325 7230
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pajhooheshi@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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Position
Research Assistant

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Person responsible for updating data

Contact

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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@sbmu.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