# 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@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
**City**
sari
**Province**
Mazandaran
**Postal code**
4817844718
**Phone**
+98 11 3325 7230
**Email**
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
**Street address**
Deputy for Research and Technology Building, Moallem Square, Sari
**City**
Sari
**Province**

Mazandaran

**Postal code**
4817844718

**Phone**
+98 11 3325 7230

**Email**
mehdi_hashemi@sbmu.ac.ir

## Person responsible for scientific 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

**Street address**
Deputy for Research and Technology Building, Moallem Square, Sari

**City**
Sari

**Province**
Mazandaran

**Postal code**
4817844718

**Phone**
+98 11 3325 7230

**Email**
mehdi_hashemi@sbmu.ac.ir

## Person responsible for updating data

**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

**Street address**
Deputy for Research and Technology Building, Moallem Square, Sari

**City**
Sari

**Province**
Mazandaran

**Postal code**
4817844718

**Phone**
+98 11 3325 7230

**Email**
mehdi_hashemi@sbmu.ac.ir

## 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**