Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Therapeutical effect of combined pulsed electromagnetic field and laser photobiomodulation on temporomandibular joint after condyle and sub-condylar fractures treated with closed reduction

Protocol summary

Study aim

The effect of combining pulsed magnetic field and laser photobiomodulation on temporomandibular joint function after closed treatment of condylar and subcondylar fractures with long-term follow-up

Design

A controlled, parallel-group, double-blind, randomized clinical trial. Simple randomization will be followed in the study.

Settings and conduct

After the operation, the same protocol of wire fixation for 2 weeks and then elastic fixation for 4 weeks will be applied to the patients. After the fixation period is completed, based on the degree of mouth opening, if it is less than 30 mm or there is pain in the fracture area, In the intervention group, stimulation will be performed in 10 sessions (3 sessions per week). Infrared laser in a low-power manner and a low-intensity magnetic field that does not have any clinical complications. The time of each session will be 15 minutes.

Participants/Inclusion and exclusion criteria

Patients who have suffered condylar or subcondylar fractures of the mandible and have undergone closed treatment with intermaxillary fixation. Patients under 18 years of age, patients with previous condylar or subcondylar fractures of the mandible or temporomandibular joint disorders, and patients with simultaneous coronoid and zygomatic arch fractures were excluded from the study.

Intervention groups

Patients will be divided into two groups: Group 1: Control group or temporomandibular joint physiotherapy group using conventional methods (warm compresses, abseiling therapy, and finger exercises) and Group 2: Temporomandibular joint physiotherapy group using conventional methods plus a combination of pulsed magnetic field and laser photobiomodulation.

Main outcome variables

Maximum anterior jaw opening Amount of protrusive and latrosive movements of mandible Pathological sounds in the temporomandibular joint Amount of pain in the temporomandibular joint area

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250801066715N1**
Registration date: **2025-08-11, 1404/05/20**
Registration timing: **prospective**

Last update: **2025-08-11, 1404/05/20**
Update count: **0**

Registration date

2025-08-11, 1404/05/20

Registrant information

Name
Milad Baseri
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Iran (Islamic Republic of)
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2026-07-23, 1405/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Therapeutical effect of combined pulsed electromagnetic field and laser photobiomodulation on temporomandibular joint after condyle and sub-condylar fractures treated with closed reduction

Public title
Therapeutical effect of combined electromagnetic field and laser on jaw joint after condylar fractures treated with closed reduction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have isolated fractures of the head or neck of the condyle or subcondylar mandible. Patients who have only undergone closed treatment with intermaxillary fixation Patients who experience limitation in opening the mouth or pain in the fracture area after a 6-week fixation period.
Exclusion criteria:
Patients with previous temporomandibular joint disorders Patients with previous surgeries in the temporomandibular joint area, including temporomandibular joint replacement. Patients who have limited mouth opening or progressive and lateral movements prior to the fracture Patients with a history of previous condylar and subcondylar fractures Patients with concomitant fractures of the coronoid, zygomatic arch, or zygomaticomaxillary complex Patients with any systemic diseases related to bones and joints Patients whose condylar and subcondylar fractures have been treated open Patients whose fractures were caused by fighting
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization based on the Lot system with an allocation ratio of 1:1 will be followed in the study. This randomization sequence will be performed using the Random Allocation Method (Windows software version 2.0) and allocation will be done in opaque sealed envelopes. The software generates random numbers for each patient who intends to enter the study. Based on the initial agreement to assign even and odd numbers to the study groups, these random numbers will be used to assign participants to the groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The outcome assessor who will assess the patient during follow-up will be blinded to the type of physiotherapy given to that individual. The data analyst will also be blinded to the study groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committees of Research Institute of Dental Sciences- Shahid Beheshti University of M
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1985717443
Approval date
2025-07-26, 1404/05/04
Ethics committee reference number
IR.SBMU.DRC.REC.1404.024

Health conditions studied

1

Description of health condition studied
Mandibular condylar and subcondylar fractures
ICD-10 code
S02.6
ICD-10 code description
Fracture of mandible

Primary outcomes

1

Description
Maximum anterior jaw opening
Timepoint

Before surgery and 1, 3, 6, and 12 months after surgery

Method of measurement

Graduated ruler

Secondary outcomes

1

Description

The amount of protrusive and latrosive movement of the mandible

Timepoint

Before surgery and 1, 3, 6, and 12 months after surgery

Method of measurement

Graduated ruler

2

Description

Pain in the temporomandibular joint area

Timepoint

Before surgery and 1, 3, 6, and 12 months after surgery

Method of measurement

Based on patient opinions and VAS scale

3

Description

Pathological sounds in the temporomandibular joint

Timepoint

Before surgery and 1, 3, 6, and 12 months after surgery

Method of measurement

Based on clinical examinations

Intervention groups

1

Description

Control group: Temporomandibular joint physiotherapy group using conventional methods (warm compresses, abseiling therapy, and finger exercises)

Category

Rehabilitation

2

Description

Intervention group: Temporomandibular joint physiotherapy group using the conventional method plus a combination of pulsed magnetic field and laser photobiomodulation.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Fereydoun Pourdanesh

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2

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Shahid Beheshti 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
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Position
Resident
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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