

# 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 subcondylar 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

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2242 6086

##### Email address

miladbaseri1377@gmail.com

##### 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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Dentistry Faculty, Shahid Beheshti University of Medical Sciences, Velenjak St., Shahid Chamran Highway

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Tehran

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**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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Shahid Chamran Highway, Yemen Street - Shahid Arabi Street, next to Shahid Beheshti University of Medical Sciences

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**2**

**Recruitment center**

**Name of recruitment center**

Imam Hossein Hospital

**Full name of responsible person**

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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****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Milad Baseri

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Oral and Maxillofacial Surgery

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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