

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Double blind randomized clinical trial of therapeutic effect of low level laser therapy on acute pain and mouth opening after closed reduction of condylar fracture.

Protocol summary

Study aim

Evaluation of the therapeutic effect of low-level laser therapy on acute post-operative pain and mouth opening in patients undergone a closed reduction of the temporomandibular joint fracture.

Design

A randomized double blind clinical trial consisting of two groups each one has 20 cases, will be performed from June 2020 till September 2020.

Settings and conduct

The study will be performed in the department of oral and maxillofacial surgery of Kerman Bahonar hospital and Kerman university of dentistry. Both patients and researcher aren't aware of the type of intervention and the operator is the only person who knows the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men and women with an isolated traumatic fracture of temporomandibular joint which are closed-treatment candidates. Exclusion criteria: patient suffering pathologic fracture, patient with fracture which needs to be treated with open surgery, pregnant women, underaged patient with mixed dentition, edentulous patients, patient with a known history of pain diseases, patient with intellectual disability who are not able to fill in the questionnaire

Intervention groups

Control group: Use of inactive LLT+standard protocol of closed reduction of the temporomandibular fracture.
Intervention group: Use of inactive LLT+ standard protocol of closed reduction of the temporomandibular joint.

Main outcome variables

Visual Analogue Scale(VAS), Degree of mouth opening measured by interincisal distance in millimeters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200520047519N1**

Registration date: **2020-06-09, 1399/03/20**

Registration timing: **prospective**

Last update: **2020-06-09, 1399/03/20**

Update count: **0**

Registration date

2020-06-09, 1399/03/20

Registrant information

Name

arash bahari bandari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 9021

Email address

a.bahari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double blind randomized clinical trial of therapeutic effect of low level laser therapy on acute pain and mouth opening after closed reduction of condylar fracture.

Public title

Evaluation of effect of laser on TMJ fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Trauma patients with TMJ fracture that need closed reduction (archbar and maxillomandibular fixation).

Exclusion criteria:

Subcondylar fractures that need Open Reduction and Internal Fracture (ORIF) Pathologic fractures Patient who cannot complete follow-up sessions Patient with craniofacial deformity Pregnant woman Patient that aren't able to fill in questionnaire Patients who suffer from major associated traumatic injuries or systemic conditions.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed utilizing computer software using block randomization method and 5 patient within a block

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient and the person who evaluate the treatment outcomes will be blind to the patient's groups. During the first visit, patients will be explained about the probability of being chosen for any of the groups. Before treatment sessions, one of the staff who is not involved in the research will extract the patient information from a sealed envelope and will deliver the laser device's parameters to an operator who either is not involved in the research. Patients and the practitioner won't be informed about the method which has been used. The device's sound is similar for both groups and all patients will be blindfolded by the security eyewear.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical sciences. ical science

Street address

kerman University of Medical Science, Medical University Campus, Haftbagh ighway, Kerman, Iran

City

kerman

Province

Kerman

Postal code

7618759689

Approval date

2020-06-09, 1399/03/20

Ethics committee reference number

IR.KMU.REC.1399.148

Health conditions studied

1

Description of health condition studied

Temporomandibular Joint Fracture

ICD-10 code

S02.92XA

ICD-10 code description

Unspecified fracture of facial bones, initial encounter for closed fracture

Primary outcomes

1

Description

Acute postoperative pain in a patient who have undergone a close reduction of temporomandibular joint fracture

Timepoint

VAS will be recorded 24, 48 and 72 hours after surgery.

Method of measurement

Visual Analogue scale

2

Description

Degree of mouth opening

Timepoint

7 days after surgery

Method of measurement

ruller

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Gallium-Aluminum-Arsenide laser, 808nm, 3J/cm³, 20 s sessions of laser therapy will be performed while the probe tip has approximately 2mm distance from skin surface, on 14 extra oral points (8 points on masseter, 2 point in pre auricular are, 2 submandibular and 2 point in jugulodigastric area). each time an area of 1.5 mm² will be treated.

Category

Treatment - Devices

2

Description

Control group: Intervention in this group will be the same as the intervention1 except the device will be used in inactive mode.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and Maxillofacial surgery Department- Kerman Bahonar Hospital

Full name of responsible person

Saeid Hajmohammadi

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Qarani St.

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arash.bahari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Moluk Torabi

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Arash Bahari Bandari

Position

resident

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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome only

When the data will become available and for how long

6 month after publication

To whom data/document is available

For academic use will be accessible

Under which criteria data/document could be used

For further research

From where data/document is obtainable

Email: a.bahari@kmu.ac.ir

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

Requests must be applied by Email.

Comments