

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effects of low power laser on temporomandibular joint after maxillofacial surgery

Protocol summary

Study aim

Evaluation of the effects of a period (ten sessions) of using low power laser on temporomandibular joint after maxillofacial cosmetic surgery, swelling, limitation of movement and quality of life.

Design

McGill and SF36 Persianized pain questionnaires will be completed by the patient in the first, fifth and tenth sessions. Also, the amount of pain before the start of each treatment session will be measured and recorded according to VAS. Each session before the start, the amount of swelling and the amount of range of motion of the jaw in the vertical direction will be measured and recorded.

Settings and conduct

This study will be performed in Shahid Beheshti School of Rehabilitation of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with mandibular protrusion who underwent bilateral jaw split sagittal surgery. 2- Age range 15 to 40 years. 3- A maximum of two weeks had passed since the date of surgery. 4- Jaw movements in the direction of vertical opening were limited to less than 4 cm. exclusion criteria: unwillingness to complete sessions and lack of patient cooperation.

Intervention groups

Intervention group: The patient will be lying down in the dental unit i. The radiation site will be considered as 5 point. To protect the patient's eyes, the patient will wear protective goggles throughout the treatment. Possible side effects of the laser will be investigated. The approximate duration of each session will be approximately 20 minutes. The number of sessions will be 10 sessions in two weeks. Control group: using the device off and in this group the number of sessions of 10 sessions in two weeks will be considered.

Main outcome variables

the pain Inflammation Range of motion Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151128025265N4**

Registration date: **2021-06-23, 1400/04/02**

Registration timing: **prospective**

Last update: **2021-06-23, 1400/04/02**

Update count: **0**

Registration date

2021-06-23, 1400/04/02

Registrant information

Name

Sedigheh Sadat Naimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 1411

Email address

naimi.se@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-05, 1400/08/14

Expected recruitment end date

2023-01-04, 1401/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of low power laser on temporomandibular joint after maxillofacial surgery

Public title

Effects of low power laser after maxillofacial surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

1- Patients with mandibular protrusion who underwent bilateral jaw split sagittal surgery. 2- Age range 15 to 40 years. 3- A maximum of two weeks had passed since the date of surgery. 4- Jaw movements in the direction of vertical opening were limited to less than 4 cm.

Exclusion criteria:

unwillingness to complete sessions and lack of patient cooperation.

Age

From **15 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with mandibular protrusion after cosmetic reconstructive surgery were selected by simple and available sampling and randomly divided into two groups: intervention (n: 18) and control (n: 18). In this study, for random allocation, the coin tossing method was used in such a way that one group is considered a lion and one group is considered a line and people are randomly divided into two groups according to the number of taps and lines.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Tehran - Imam Hossein (AS) Square - Damavand St.

(New Tehran) - in front of Bouali Hospital - Faculty of Rehabilitation Sciences Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1616913111

Approval date

2021-06-12, 1400/03/22

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.125

Health conditions studied**1****Description of health condition studied**

the effects of laser on Temporomandibular joint

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes**1****Description**

Intensity of pain

Timepoint

Before and after the intervention

Method of measurement

visual analuge scale

2**Description**

inflammation

Timepoint

Before and after the intervention

Method of measurement

Flexible centimeters

3**Description**

Movement restrictions

Timepoint

Before and after the intervention

Method of measurement

Collis

4**Description**

McGill Pain Questionnaire

Timepoint

Before and after the intervention

Method of measurement

questionnaire

5

Description

Quality of Life Questionnaire

Timepoint

Before and after the intervention

Method of measurement

Quality of Life Questionnaire SF36

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient was lying down in the dental unit in a state of physical and mental relaxation. The irradiation site was considered as 5 points on the operation line to reduce pain and swelling and 5 points on the joint to increase movement. The laser probe was sterilized with an alcohol swab in each session and each time it was used. The approximate duration of each session was about 20 minutes. The number of sessions was 10 sessions in two weeks

Category

Rehabilitation

2

Description

Control group: Laser device off

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation, Shahid Beheshti University of Medical Science

Full name of responsible person

Sedigheh Sadat Naimi

Street address

Damavand St., in front of Bouali Hospital, Shahid Beheshti Rehabilitation Faculty

City

Tehran

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Postal code

1616913111

Phone

+98 21 7754 8496

Email

naimi.se@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Tehran - Shahid Chamran Highway - Yemen Street - next to Taleghani Hospital - Shahid Beheshti University of Medical Sciences

City

tehran

Province

Tehran

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1985717443

Phone

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Fax

+98 87 95008

Email

zarghi@sbmu.ac.ir

Web page address

https://isid.research.ac.ir/Afshin_Zarghi

Grant name

Shahid Beheshti University of Medical Science

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Dr. Afshin Zarghi

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

Sedigheh Sadat Naimi

Position

associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Tehran - Imam Hossein Square - Damavand St. (New Tehran) - in front of Bouali Hospital - Faculty of Rehabilitation Sciences Shahid Beheshti University of Medical Science

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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