

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Investigation of the effects of three conservative treatment methods on temporomandibular disorders

Protocol summary

Study aim

To compare the effect (short-term and long-term) of three treatment methods using splint, low level laser and combination of low level laser and splint on complications of TMD.

Design

This study is a randomized clinical trial.

Settings and conduct

30 patients with orofacial pain who are referred to the Department of the prosthesis at Dental School of Shahid Beheshti University of Medical Sciences, Tehran, are recruited according to the mentioned inclusion and exclusion criteria. All patients are examined and diagnosed with a temporomandibular joint disorder according to RDC / TMD criteria are included in the study. The patient is asked to sign the informed consent form. Patients are randomly allocated to three groups of stabilization splint, low power laser therapy, and combination therapy (low power laser + stabilization splint).

Participants/Inclusion and exclusion criteria

Major inclusion criteria: Age 18-60, Chronic orofacial pain (more than three months) with or without restriction in opening the mouth, Diagnosis of Temporomandibular disorder (pain-related or intra-articular disorders) based on the RDC / TMD diagnostic criteria. Major exclusion criteria: Recent fracture of mandibular bone, History of recent facial trauma, Congenital/developmental disorders of the jaw, History of previous treatment for TMD during the last month, Systemic musculoskeletal disease, Fibromyalgia., Previous or current history of cancer, Skin lesions at the laser site, Pregnancy.

Intervention groups

Three groups: Stabilization splint treatment, low-level laser treatment, and combination treatment (low-level laser + Stabilization splint).

Main outcome variables

Outcomes include the severity of pain, the extent of maximal opening of the patient's mouth, the extent of

the patient's maximum ability to perform lateral and anterior mandibular movements, and the extent of limitation of jaw functions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211010052719N1**

Registration date: **2021-10-26, 1400/08/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-26, 1400/08/04**

Update count: **0**

Registration date

2021-10-26, 1400/08/04

Registrant information

Name

Mahdi Shamali

Name of organization / entity

University of Southern Denmark

Country

Denmark

Phone

+45 65 50 10 00

Email address

mshamali@health.sdu.dk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-10, 1399/06/20

Expected recruitment end date

2021-12-30, 1400/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effects of three conservative treatment methods on temporomandibular disorders

Public title

Investigation of the effects of three conservative treatment methods on temporomandibular disorders

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic orofacial pain (more than three months) with or without restriction in opening the mouth. Diagnosis of Temporomandibular disorder (Axis I) based on the RDC / TMD diagnostic criteria. History of no previous treatment for TMD during the last month. Having natural dentition

Exclusion criteria:

Recent fracture of mandibular bone. History of recent facial trauma Congenital / developmental disorders of the jaw. Systemic musculoskeletal disease. Fibromyalgia. Previous or current history of the cancer. Skin lesions at the laser site. Pregnancy. Diagnosis of Temporomandibular disorder of articular origin based on the RDC / TMD diagnostic criteria.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly allocated to 3 treatment groups. A central randomization unit was contacted by phone to ensure allocation concealment and assign the enrolled patient to each treatment group. The central randomization unit had prepared a list of numbers from 1 to 30 that were allocated randomly to 3 equal groups using a website (<https://www.random.org>) which generated a list of random numbers in 3 columns. Before randomization, the first column was considered the Stabilization splint treatment group, the second column the low level laser treatment group, and the third column the combination treatment group (low level laser + Stabilization splint).

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**

the Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2020-09-09, 1399/06/19

Ethics committee reference number

IR.SBMU.DRC.REC.1399.042

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

Temporomandibular disorders

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

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

Pain intensity

Timepoint

Before treatment, immediately after treatment, one month and three months after the end of treatment

Method of measurement

visual scale analogue (VAS)

2**Description**

Maximum mouth opening with NO assistance

Timepoint

Before treatment, immediately after treatment, one month and three months after the end of treatment

Method of measurement

By ruler in millimeters

3

Description

Right & left and anterior lateral movement of mandible

Timepoint

Before treatment, immediately after treatment, one month and three months after the end of treatment

Method of measurement

By ruler in millimeters

4

Description

Functional limitations of jaw

Timepoint

Before treatment, immediately after treatment, one month and three months after the end of treatment

Method of measurement

visual scale analogue (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Stabilization splint treatment group: Splints are made according to Okeson's instructions and necessary adjustments are made. The patient is instructed to use the splint for 12 hours a day for three months. The outcomes are evaluated at intervals before splint treatment, one month, three months, after the start of treatment.

Category

Treatment - Devices

2

Description

Low level Laser treatment group: A diode laser device, noncontact mode, continuous wave, 0.1 W (100 mW), 810 nm, 6 J / cm, 2,60 s / session are used, which is performed in three sessions per week for three weeks (A total of nine sessions). The laser is applied to the origin, insertion, and body areas of the masseter muscle and the anterior, middle, and posterior parts of the temporalis muscle , as well as to the center of the upper joint space, about one cm in front of the tragus. The outcomes are evaluated at intervals before splint treatment, one month, three months, after the start of treatment.

Category

Treatment - Devices

3

Description

Combination treatment group: This group of treatments is initially treated with low level laser according to the mentioned protocol. Then, immediately after the end of

the laser treatment, they are treated with a splint according to the protocol for three months. The outcomes are evaluated at intervals before splint treatment, one month, three months, after the start of treatment.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Afshari

Street address

Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9770

Email

afsharyzhra1@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 21 2243 9780

Email

info@sbmu.ac.ir

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

70

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

Zahra Afshari

Position

Resident of Prosthodontics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 31 5366 4431

Email

afsharyzhr1@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Afshari

Position

Resident of Prosthodontics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

19839-63113

Phone

+98 31 5366 4431

Email

afsharyzhr1@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

University of Southern Denmark

Full name of responsible person

Mahdi Shamali

Position

Post doc

Latest degree

Ph.D.

Other areas of specialty/work

Health sciences

Street address

Campusvej 55

City

Odense

Province

Fyn

Postal code

5230 Odense

Phone

+45 65 50 10 00

Email

gezaltoshmal@yahoo.com

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