

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of conventional and digital occlusal splints with low power lasers in the treatment of patients with temporomandibular disorders

Protocol summary

Study aim

The aim of this study is to investigate the short term and long term therapeutic effects of low level laser therapy along with the use of conventional and digital occlusal splint in treatment of tmd patient

Design

A concealed, randomized, unblinded, sham controlled clinical trial with two parallel group designed among 40 patient. the rand function of excel software was used for randomization

Settings and conduct

The place of study: department of dental prostheses, shahid beheshti dental school, Tehran
population: tmd patient
blinding: blinding was not done in this study

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of patient between 20 and 50 years, diagnosis of TMD based on DC/TMD and RDC/TMD criteria. exclusion criteria: history of recent facial trauma, congenital or developmental disorder of the jaw, history or presence of systemic musculoskeletal disease, history or presence of cancer, pregnancy, history of previous treatment of TMD during the last month, using complete denture.

Intervention groups

1. Treatment with conventional occlusal splint
2. Treatment with conventional occlusal splint with low level laser therapy
3. Treatment with digital occlusal splint
4. Treatment with digital occlusal splint with low level laser therapy

Main outcome variables

Jaw motion limitation, discoloration, wear resistance and chair time in occlusal splints

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220706055400N1**

Registration date: **2023-02-20, 1401/12/01**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-20, 1401/12/01**

Update count: **0**

Registration date

2023-02-20, 1401/12/01

Registrant information

Name

hossein akbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 29901

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hosseinakbari716@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of conventional and digital occlusal splints with low power lasers in the treatment of patients with temporomandibular disorders

Public title

Effect of low level laser therapy and occlusal splint in treatment of TMD patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age Between 20 and 50 years, diagnosis of TMD based on DC/TMD and RCT/TMD criteria, click problems, limitation in maximum mouth opening and chronic orofacial pain more than 3 months.

Exclusion criteria:

History of recent facial trauma, congenital disorders, history of recent facial fracture, history or presence of recent musculoskeletal diseases, history or presence of cancer History or presence of skin problems, history or previous treatment History or presence of psychological disorders, Patient with odontogenic pain Complete denture patient Periodontal disease

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The rand function of excel software was used for randomization, the allocation of patient to 4 treatment group is done in the form of randomization blocks. so that 5 blocks of 6 are defined, and in each of these blocks, the order of treatments is generated randomly with the excel program. Patients receive random treatment in these randomized blocks in the order of referral.

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 Science

Street address

Daneshjoo blvd, evin, Shahid Chamran highway, tehran city

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.SBMU.DRC.REC.1401.041

Health conditions studied

1

Description of health condition studied

Temporomandibular disorder

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes

1

Description

Intensity of spontaneous pain

Timepoint

Spontaneous pain measurement before the study, 30 days after the completion of the laser therapy period, 30 and 90 days after using the occlusal splint

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Occlusal splint discoloration

Timepoint

After 3 and 6 months

Method of measurement

After observation by clinician

2

Description

Time of occlusal splint adjustment

Timepoint

Delivery appointment

Method of measurement

By watch chronometer

3

Description

Occlusal splint wear resistance

Timepoint

After 3 and 6 months after delivery

Method of measurement

By gauge

4

Description

Patient satisfaction

Timepoint

After 3 and 6 month of delivery

Method of measurement

By question of patient

5

Description

Maximum mouth opening

Timepoint

Measurement of the maximum opening before the study 30 day after completion the laser treatment period,30 and 90 day after using digital occlusal splint

Method of measurement

Using a ruller in milimeter scale

Intervention groups

1

Description

Intervention group:Use diode laser with 300mA bilaterally in 10 seconds in superior,middle and inferior region of masseter and temporal, sternocleidomastoid and then use conventional occlusal splint for 6 month

Category

Treatment - Devices

2

Description

Intervention group: Intervention group: Use diode laser with 300mA bilaterally in 10 seconds in superior,middle and inferior region of masseter and temporal, sternocleidomastoid and then use Digital occlusal splint for 6 month

Category

Treatment - Devices

3

Description

Intervention group: use Digital occlusal splint for 6 month

Category

Treatment - Devices

4

Description

Intervention group: use conventional occlusal splint for 6 month

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of dental prostheses, Shahid Beheshti faculty of dentistry

Full name of responsible person

Hossein akari

Street address

Shahid Beheshti faculty of dentistry, Shahid Beheshti university of medical sciences, Daneshjoo Blvd, Evin Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice president of research and Technology of Shahid Beheshti University of Medical Sciences

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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

Rahab ghoveyzi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Position

Associate professor

Latest degree

Specialist

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All patients data including age,sex and results research will be shareable after making individuals undistinguishable

When the data will become available and for how long

As the same time as publishing results

To whom data/document is available

Researchers in academic and scientific intitutions

Under which criteria data/document could be used

Quantitative analyzes on the results are allowed

From where data/document is obtainable

Hossein Akbari 00989166645663

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

After receiving e-mail from applicant,it will take up to one month to sent documents.

Comments