Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of therapeutic effect of low level laser therapy and laser acupuncture in patients with myofascial pain dysfunction syndrome

Protocol summary

Summary

The aim of this study is to compare effect of low level laser therapy with laser acupuncture in improving pain in patient with myofascial pain dysfunction syndrome. This study is designed as randomized, controlled, double blind, one center, Clinical trial in phase III and involving 40 patients with MPDS. The main inclusion criteria are patients with MPDS and history of chronic pain (more than 3 months) and history of chronic pain≥4 according to VAS a signed statement of inform consent . Main exclusion criteria will be included lack of acceptable cooperation, psychological disorders, current trauma, current pregnancy, Epidermal cancer, proliferative disease, febrile or infectious disease, epilepsy, diabetes mellitus, thyroid disorders and patients who use muscle relaxant and tranquilizer agents during the time of study. Patients randomly is divided to two groups, including low level laser therapy (LLLT) and laser acupuncture (LA). In LLLT group, patients will receive diode laser radiation in one month period along with 12 sessions at the trigger points of masticatory muscles. In laser acupuncture group, patients will receive diode laser radiation in one month period along with 12 sessions at the acupuncture points. The pain intensity of patients and their maximum mouth opening will be measured before and during treatment period and 2 months after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102124631N1**
Registration date: **2016-04-26, 1395/02/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-26, 1395/02/07

Registrant information

Name
Parvin Parvaie
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2217 5351
Email address
parvin.parvaie@yahoo.com

Recruitment status

Recruitment complete

Funding source
Shahid Beheshti University of Medical Sciences, Shahid Behesti Dental School, Research Assistance

Expected recruitment start date
2015-01-21, 1393/11/01

Expected recruitment end date
2016-04-18, 1395/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of therapeutic effect of low level laser therapy and laser acupuncture in patients with myofascial pain dysfunction syndrome

Public title

comparing the effect of laser and laser acupuncture in treatment of masticatory muscles pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with a myofascial pain dysfunction syndrome and history of chronic pain(more than 3 months); history of chronic pain≥4 according to VAS; A signed statement of inform consent Exclusion criteria: lack of acceptable cooperation; psychological disorders; current trauma; current pregnancy; Epidermal cancer; proliferative disease; febrile or infectious disease; epilepsy; diabetes mellitus; thyroid disorders; patients who use muscle relaxant and tranquilizer agents during the time of study

Age
From **10 years** old to **75 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

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Science

Street address
Shahid Beheshti Dental school, Daneshjoo Blvd, Evin, Chamran Highway

City
Tehran

Postal code
1983963113

Approval date
2016-02-10, 1394/11/21

Ethics committee reference number
IR.SBMU.RIDS.REC.1394.100

Health conditions studied

1

Description of health condition studied
myofascial pain disorder syndrom

ICD-10 code
k07.6

ICD-10 code description
Temporomandibular joint disorders

Primary outcomes

1

Description
Pain

Timepoint
before the treatment; during treatment; 2 monthes after the end of treatment

Method of measurement
patient asked about her/his pain according VAS criteria

2

Description
Maximum mouth opening

Timepoint
before the treatment; during treatment; 2 monthes after the end of treatment

Method of measurement
the distance of between incisal edge of the anterior teeth in m

Secondary outcomes

1

Description
jaw deviations

Timepoint
before the treatment, during treatment, 2 monthes after the end of treatment

Method of measurement
inspection of the deviation from facial midline at the time of mouth opening and closing

Intervention groups

1

Description
Intervention A: In LLLT group patients will receive the laser radiation every day in the first week for 5 day and every other day in the second week and in 2 session in each of third and fourth week. The GA-AL-AS diode laser with a wave length of 808 nm in continuous mode will be used and radiation is carried out in contact method and follow up of the patients is accomplished 2 month after the end of treatment and the pain intensity, maximum mouth opening will be measured in this session.

Category
Treatment - Devices

2

Description
Intervention B: In LA group, patients will receive the laser

acupuncture treatment in 3 day in every week for 4 week. All of the patients in this group will receive the GA-AL-AS diode laser radiation with a wave length of 808 nm and power of 150 mw in each point for 5 sec in 3 acupuncture point and for 40 sec in painful point of each muscle with power density of 5 w/cm2 and energy density of 7.5-26.25 J/cm2. Laser radiation will be carried out by a specific hand piece of low level laser with a diameter of 9 mm by contact of the hand piece tip to the points that mentioned above.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Universiyt of Medical Sciences, Dental School, Oral Medicine Department

Full name of responsible person

Dr Hamidreza Khalighi

Street address

Shahid Beheshti Dental School, Daneshjoo Blvd, Evin, Chamran Highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti Dental School, Research Assistance

Full name of responsible person

Dr Azita Tehranchi

Street address

Shahid Beheshti Dental School, Daneshjoo Blvd, Evin, Chamran Highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti Dental School, Research Assistance

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences, Shahid Beheshti Dental School, Oral Medicine Departm

Full name of responsible person

Parvin Parvaie

Position

Oral Medicine Post Graduated Student

Other areas of specialty/work

Street address

Shahid Beheshti Dental School, Daneshjoo Blvd, Evin, Chamran Highway

City

Tehran

Postal code

Phone

+98 21 2990 2311

Fax

Email

parvin.parvaie@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences, Shahid Beheshti Dental School, Oral Medicine Departm

Full name of responsible person

Dr Hamidreza Khalighi

Position

Assistance Professor

Other areas of specialty/work

Street address

Shahid Beheshti Dental School, Daneshjoo Blvd, Evin, Chamran Highway

City

Tehran

Postal code

Phone

+98 21 2990 2311

Fax

Email

dr.hrkh92@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti Universiyt of Medical Sciences, Dental School, Oral Medicine Department

Full name of responsible person

Parvin Parvaie

Position

Oral Medicine Post Graduated Student

Other areas of specialty/work

Street address
Shahid Beheshti Dental School, Daneshjoo Blvd, Evin, Chamran Highway
City
Tehran
Postal code
Phone
+98 2100982129902311
Fax
Email
parvin.parvaie@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty