Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Comparing Analgesic effect of 808nm low-level laser, dry needing and cupping in the treatment of MPDS

Protocol summary

Study aim
Introducing a preferred treatment method for treating facial muscle trigger points
Design
Experimental research (blind bilateral clinical trial)
Settings and conduct
Laser Department of Shahid Beheshti Dental School
Participants/Inclusion and exclusion criteria
Sample entry criteria: 1. Age over 18 years 2. The presence of a trigger point in the temporalis or master or external trigeminal muscles, which are identified by touch and examination. Exclusion criteria: 1.Taking painkillers, muscle relaxants, anti-inflammatory drugs and benzodiazepines. 2.Tears, Cupping or laser 3. Bleeding disorders 4. Any underlying diseases such as metabolic (diabetes) and vascular 5. Neurological disorders (trigeminal neuralgia) 6. Pregnancy 7. Receive any treatment for temporomandibular joint disorder
Intervention groups
The first group will be treated with a low power laser of GA-AL-AS diode with a wavelength of 808 nm laser device In the second group, treatment with dry needling (Tony brand) made in China with a gauge (0.18 * 13 mm) will be performed on the trigger points. In the third group of Cupping patients, first the muscle trigger points in the master or temporalis or external trigeminal muscles are identified and the cupping is performed by an assistant from the oral diseases department under the supervision of a professor and specialist in pain and acupuncture.
Main outcome variables
Visual Analogue Scale VAS Maximum mouth opening MMO

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20111121008146N38**
Registration date: **2022-03-17, 1400/12/26**
Registration timing: **prospective**

Last update: **2022-03-17, 1400/12/26**
Update count: **0**
Registration date
2022-03-17, 1400/12/26

Registrant information
Name
Mohammadreza Razaghi
Name of organization / entity
Laser application in medical sciences research center
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-03-21, 1401/01/01
Expected recruitment end date
2023-03-20, 1401/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing Analgesic effect of 808nm low-level laser, dry needing and cupping in the treatment of MPDS

Public title
Comparing Analgesic effect of 808nm low-level laser, dry

needing and cupping in the treatment of MPDS

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years The presence of a trigger point in the temporalis or master or external trigeminal muscles that are identified by touch and examination

Exclusion criteria:

Taking painkillers, muscle relaxants, anti-inflammatory drugs and benzodiazepines Fear of needles, cupping or lasers Bleeding disorders Any underlying diseases such as metabolic (diabetes) and vascular Neurological disorders (trigeminal neuralgia) Pregnancy Receive any treatment for temporomandibular joint disorder

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

single-digit random numbers were generated using Excel software. The order of these random numbers was considered as the number of people entering the study. If these numbers were between 1-3, the patient was assigned to the first group, between 4-6 to the second group, between 7-9 to the third group. Following the work of each group, to which 20 patients were assigned, the generated numbers related to that group were removed from the random number production chain.

Blinding (investigator's opinion)

Double blinded

Blinding description

Clinical examination of all patients is performed by another specialized assistant of trained oral diseases under the supervision of neutral professors and the patients' details are recorded based on the information form. Relevant assistants and professors will not know that the patient belongs to the acupuncture and cupping group at any stage of the examination.

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics in Biomedical Research of Shahid Beheshti University of medical sciences

Street address

Daneshjoo Blvd, Yaman street

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Province

Tehran

Postal code

1985717443

Approval date

2022-01-09, 1400/10/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.729

Health conditions studied

1

Description of health condition studied

myofascial trigger points pain syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain

Timepoint

Pain is recorded in the first session of the examination under VAS 1 and then in each treatment session at the beginning of the session before the start of the new treatment phase that day in the relevant schedule. The last amount of pain recording in the follow-up session is done 1 month after the completion of the treatment sessions as VAS 2 or Visit In 1 Month.

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

(Maximum mouth opening)

Timepoint

In the first session, the examination is called MMO 1 and each session is recorded in the relevant table before starting the treatment. The last MMO registration in the follow-up session is done 1 month after the completion of the treatment sessions as MMO2 or Visit In 1 Mouth.

Method of measurement

By calibrated ruler in mm

Intervention groups

1

Description

Intervention group:The first group is treated with GA-AL-AS low power diode laser with a wavelength of 808 nm Konftec low power laser device made in Taiwan with a power of 250 ml watts for 60 seconds with a power of 15J and a density of 4 joules per square centimeter It is used at any point of the trigger as a Continuous Wave and the laser irradiation is done in contact with the gentle pressure of the device type with a Spot Size of 3 cubic centimeters in the irradiation area. First, the points of the muscle trigger are identified in the management of the master or temporalis or external trigoid, and then laser irradiation will be performed on the points. The number of treatment sessions will be 3 times a week, one day in between and a total of 8 sessions

Category

Treatment - Other

2

Description

Intervention group: In the second group, treatment with dry needling (Tony brand) made in China with a gauge (0.18 * 13 mm) will be performed on the trigger points. First we find the available trigger points and copy them with a pencil. To find trigger points, touch the muscle with medium to high pressure in all its parts. When the point of the muscle trigger was found, which was actually a relatively hard nodule to the touch, mark the skin of the trigger with a disinfected copy pencil, disinfect the skin with medical alcohol, and treat under the supervision of a professor. We start with a pain specialist and acupuncturist. Insertion of needle is gentle and 5 to 10 mm deep, uniform and intentional. If there is no reaction after the needle enters, the needle should stay in place for 2 to 3 minutes and then be removed.

Category

Treatment - Other

3

Description

Intervention group: In the third group of cupping patients, first the muscle trigger points in the master or temporalis or external trigeminal muscles are identified and cupping is performed by an assistant from the oral diseases department under the supervision of a professor and specialist in pain and acupuncture. Cupping does not have a lasting effect on the skin, it only causes temporary redness in some people. This treatment is vacuumed with a 10 cc disposable cup in the desired places with suction or vacuum hand tools to the extent that 1 cm of skin is highlighted under the vacuum inside the cup and stays on the place for 5 minutes with the same amount of negative pressure. It is repeated every other day

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Mohammad Asnaashari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sadi Banar

Street address
Laser Application in Medical Sciences Research Center, Shohadaye-Tajrish Educational Hospital, Tajrish Sq, Tehran, Iran

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1989934370

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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
Dr Mohammad Asnaashari

Position
professor of shahid beheshti university of medical sciences

Latest degree
Subspecialist

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
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Dentists. Oral and maxillofacial surgeons

Under which criteria data/document could be used
Email the corresponding author and earn permission

From where data/document is obtainable
Email the corresponding author

What processes are involved for a request to access data/document
Email the corresponding author, the authors' meeting, send the data at your discretion

Comments