Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of low level laser therapy on myofacial trigger points of cervical muscles in patients with cervicogenic headache.

Protocol summary

Summary

Objectives: The aim of the present study is to evaluate the effect of low level laser therapy (LLLT) on trigger points (TPs) of upper Trapezius, Sternocleidomastoid and Temporal muscles. Design: This is a randomized clinical trial. Setting and conduct: The study population are the patients with cervicogenic headache (CGH). Thirty Patients based on inclusion criteria will be participated in the present study. Patients will be randomly divided in 3 groups: a control group as group 1 (which have their prescribe medication), a sham group ("laser off" on the TPs) as group 2 and a treatment group ("laser on" for the TPs) as group 3. Major Inclusion criteria: patients between 18 to 40 years old; existence of minimum one trigger point in upper trapezius muscle with or without existence of trigger points in other 2 muscles of the present study; more than 10 degree limitation in cervical flexion or rotation to each side. Major Exclusion criteria: history of fracture in cervical region; pregnancy; history of whiplash injury and neck surgery; any conservative treatment during the last 3 months before starting the present study. Intervention: a low power laser with intensity of 11 joules and frequency of 3 Kilohertz will be used for laser therapy. There will be 6 sessions' treatments within 2 weeks for groups 2 and 3. The variables will be measured two weeks before the first session and two weeks after the last session (follow up phase). Main outcome measures (variables): Head Disability Index (HDI), intensity and duration of headache and also active cervical range of motion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030118754N5**
Registration date: **2017-04-22, 1396/02/02**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-04-22, 1396/02/02

Registrant information

Name

Javad Sarrafzadeh

Name of organization / entity

Iran University of Medical Sciences, School of Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-10-07, 1397/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low level laser therapy on myofacial trigger points of cervical muscles in patients with cervicogenic headache.

Public title

The effect of laser therapy on pain of patients with

cervicogenic headache.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with cervicogenic headache (CGH) and between 18 to 40 years old; existence of minimum one trigger point in upper trapezius muscle with or without existence of trigger points in other 2 muscles of the present study; more than 10 degree limitation in cervical flexion and/or rotation to each side.
Exclusion criteria: any congenital deformity; long time usage of corticosteroids or anti-inflammatory and anti-analgesic drugs; history of fracture in cervical region; herniated disc; rheumatoid arthritis; pregnancy; history of whiplash injury and neck surgery; any conservative treatment during the last 3 months before starting the present study.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Iran University of Medical Sciences

Street address

5th floor, Iran University of Medical Sciences, Hemmat highway

City

Tehran

Postal code

15459-13487

Approval date

2016-12-10, 1395/09/20

Ethics committee reference number

IR.IUMS.REC 1395.95-03-32-28292

Health conditions studied

1

Description of health condition studied

Cevicogenic headache

ICD-10 code

G44

ICD-10 code description

Other headache syndromes

Primary outcomes

1

Description

Intensity of headache

Timepoint

Two weeks Before starting the treatment sessions, before the first treatment session, at the end of treatment session and two weeks after the last treatment session

Method of measurement

Visual analog scale (VAS)

2

Description

Frequency of headache

Timepoint

Two weeks Before starting the treatment sessions, before the first treatment session, at the end of treatment session and two weeks after the last treatment session

Method of measurement

Number of headache during one week

3

Description

Active cervical flexion range of motion

Timepoint

Two weeks Before starting the treatment sessions, before the first treatment session, at the end of treatment session and two weeks after the last treatment session

Method of measurement

CROM device

4

Description

Active cervical rotation range of motion to left and right

Timepoint

Two weeks Before starting the treatment sessions, before the first treatment session, at the end of treatment session and two weeks after the last treatment session

Method of measurement

CROM device (degree)

5

Description
Pain threshold
Timepoint
Two weeks Before starting the treatment sessions, before the first treatment session, at the end of treatment session and two weeks after the last treatment session
Method of measurement
By an algometer (algometry)

6

Description
Quality of life
Timepoint
Two weeks Before starting the treatment sessions, before the first treatment session, at the end of treatment session and two weeks after the last treatment session
Method of measurement
Headache diability index (HDI) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Group 3 or intervention group: low level laser radiation with wavelength of 810 nm, in pulsed mode, with 11 joules intensity on trigger points of the 3 muscles of the present study.
Category
Rehabilitation

2

Description
Group 2 or Sham group: laser probe is placed on the trigger points of the 3 muscles of the present study but the laser device is off and patients do not know that. Patients use their prescription drugs.
Category
Rehabilitation

3

Description
Group 1 or control group: there is no intervention and patients just use their prescription drugs.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Physical therapy clinic of rehabilitation school of Iran university of medical sciences
Full name of responsible person
Javad Sarrafzadeh
Street address
Physiotherapy Clinic of School of Rehabilitation Sciences, Madadkaran street., Shahnazari street, Mirdamad street.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences, Vice chancellor for research
Full name of responsible person
Seyed Ali Javad Moosavi, Vice chancellor for research
Street address
5th Floor, Iran University of Medical Sciences, Hemmat highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences, Vice chancellor for research
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
School of Rehabilitation Sciences, Iran University of Medical Sciences
Full name of responsible person
Javad Sarrafzadeh
Position
PT, PhD in Physiotherapy, Associated Professor
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Person responsible for updating data

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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