Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of high power laser with exercise versus sham high power laser with exercise versus high power laser on pain, grip strength and function in patients with chronic lateral epicondylitis.

Protocol summary

Study aim
To evaluate the effect of high power laser in lateral epicondylitis

Design
A randomized, double blinded, sham controlled clinical trial with 3 parallel groups of about 75 participants.

Settings and conduct
This study will be conducted in physiotherapy clinic of Iran Rehabilitation School. Participants will randomly assigned to 3 groups after filling out the consent and collecting information forms. Participants and the assessor will be blinded about the groups. Evaluation will be done before treatment and at the end of the first, fifth, tenth sessions and after 3 months follow up. Intervention in the all groups includes 1 warm up session and 10 treatment sessions every other day(3 per week). After 10 treatment sessions the data will be analyzed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pain at/around the lateral epicondylitis that exacerbates by gripping; age between 35 -55 years; symptoms duration between 3-6 months; 2 of 3 positive result of provocative tests comprising Mill`s, Maudsley`s and Cozen`s tests; tenderness on palpation of lateral epicondyle Exclusion Criteria: cervical radiculopathy; neuropathy; myelopathy; any type of treatment for example: drugs; local injection and physiotherapy with in the past 3 months; upper limb surgery; deformity and fractures of elbow joint bones; pregnancy; rheumatic diseases and photo sensitivity

Intervention groups
The intervention group NO.1 will receive high power laser with exercise, the intervention group NO.2 will receive high power laser and the control group will receive sham high power laser with exercise and the effect of high power laser, high power laser with exercise and exercise on chronic lateral epicondylitis will be studied and compared.

Main outcome variables
The pain; hand grip and function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140810018754N10**
Registration date: **2019-11-29, 1398/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-29, 1398/09/08**
Update count: **0**

Registration date
2019-11-29, 1398/09/08

Registrant information

Name
Javad Sarrafzadeh

Name of organization / entity
Iran University of Medical Sciences, School of Rehabilitation Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-20, 1398/08/29

Expected recruitment end date
2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of high power laser with exercise versus sham high power laser with exercise versus high power laser on pain, grip strength and function in patients with chronic lateral epicondylitis.

Public title

The effect of high power laser in chronic lateral epicondylitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

History of the symptoms between 3 to 6 months Exacerbating the pain on lateral aspect of elbow by gripping 2 of 3 positive results of Mills-Cozen and Maudsley tests Tenderness with palpation of lateral epicondylitis

Exclusion criteria:

Cervical radiculopathy, neuropathy and myelopathy Any type of treatment; drugs, local injections and physiotherapy within the past 3 months History of upper extremity surgical treatment Deformity and fractures of the humerus and elbow joint bones Pregnancy Rheumatic disease Photosensitivity

Age

From **35 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Method: simple - unit: personal- by using sealed envelope Participants will be randomly assigned to 3 groups(intervention NO1.; intervention NO2. and control groups) by drawing a sealed envelope in which the number of one of the groups is written from a box. After completing a group it`s envelope will be put away.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants will be unaware of classification and to prevent of the participants communication, timing will arrange carefully. In the control group, the Laser set will be off. Assessor will be kept unaware and will be asked to do just evaluation and abstrain of any answer and question.

Placebo

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 Scienses

Street address

5th Floor, Iran University of Medical Science, next to Milad Tower, Hemmat Highway

City

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Province

Tehran

Postal code

1449614535

Approval date

2019-09-14, 1398/06/23

Ethics committee reference number

IR.IUMS.REC.1398.588

Health conditions studied

1

Description of health condition studied

Chronic Lateral Epicondylitis

ICD-10 code

M77.10

ICD-10 code description

Chronic Lateral Epicondylitis

Primary outcomes

1

Description

Pain

Timepoint

Before warm up session ,at the end of the first, fifth, tenth sessions and after 3 months

Method of measurement

VAS=visual analog scale

Secondary outcomes

1

Description

Hand grip strength

Timepoint

Before warm up session, at the end of first, fifth,tenth,sessions and after 3 months follow up

Method of measurement

Dynamometer

2

Description

Function

Timepoint

Before warm up session; at the end of first; fifth; tenth sessions and after 3 months follow up

Method of measurement

PRTEE Questionair= Patient Rated Tennis Elbow Evaluation

Intervention groups

1

Description

In the intervention group NO.1, intervention includes high power laser therapy and exercise. The laser parameters are: power 7 W.; energy dose 10 j/cm2; duty cycle 50%. In the first session that is a warm up the laser dose will be 5 j/cm2 and in the next ten sessions the laser dose will be 10 j/cm2. Subjects will be evaluated before the warm up; at the end of the first; fifth; tenth sessions and after 3 months follow up. During the each session, in sitting position, elbow in extension and forearm in pronation after safety precautions the treatment area will be demarcated then the laser probe will be moved along the long axis and transverse to the tendon. Exercise includes static stretching followed by eccentric exercise of wrist extensors. Stretching exercise will be performed in seated position with elbow extension and forearm pronation and wrist flexion with ulnar deviation.Stretch force will be applied by therapist according to the participant tolerance for 30 to 45 seconds and 3 times before and 3 times after eccentric exercise with 30 seconds rest between each stretch. Eccentric exercise will be performed in the seated position with elbow extension, forearm pronation and maximum wrist extension. Then the participant slowly will lower the wrist in to the flexion for a count of 30. Using the contralateral hand to return to the started position. 3 set of 10 repetition will be performed during each session with a one minute rest interval between each set for 10 sessions every other day.

Category

Treatment - Other

2

Description

Intervention group NO.2:This group receives high power laser(with the protocol as mentioned in group NO.1(laser power 5W; laser dosage 5J/CM2 in the warm up session and 10J/cm2 in the 10 treatment sessions)without exercises. Due to ethical considerations subjects will be offered the exercise after 3 months follow up.

Category

Treatment - Other

3

Description

Control group: In this group the laser unit will be off and the exercise program will be performed as the program in the intervention group NO.1. Due to ethical considerations the subjects will be offered the true treatment after 3 month follow up.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

physiotherapy clinic of School of Rehabilitation Sciences, Iran University of Medical Sciences

Full name of responsible person

Sarrafzadeh Javad

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Sponsors / Funding sources

1

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Sarrafzadeh Javad

Position

Associate Professore

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Latest degree

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Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data or results of the present study will be presented in an article or some articles that will be published after completing the study.

When the data will become available and for how long

After completing the present study and publishing the resulting article or articles

To whom data/document is available

All researchers in the field of the present study

Under which criteria data/document could be used

With the same goal as the present study and with mention of the present study as the reference. All intellectual property rights of the present study belongs to the Iran University of Medical Sciences.

From where data/document is obtainable

The corresponding author of the article or articles derived from this study

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

Written request from the author responsible for the present review after the publication of the resulting article or articles.

Comments