

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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

##### Country

Iran (Islamic Republic of)

##### Phone

00982122228051-00982122227124

##### Email address

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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 abstain 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 Sciences  
**Street address**  
5th Floor, Iran University of Medical Science, next to Milad Tower, Hemmat Highway  
**City**  
Tehran  
**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/cm<sup>2</sup>; duty cycle 50%. In the first session that is a warm up the laser dose will be 5 j/cm<sup>2</sup> and in the next ten sessions the laser dose will be 10 j/cm<sup>2</sup>. 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/CM<sup>2</sup> in the warm up session and 10J/cm<sup>2</sup> 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

##### **Street address**

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##### **Email**

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##### **Web page address**

<http://rehab.iums.ac.ir>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

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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

**Other areas of specialty/work**

Physiotherapy

**Street address**

Physiotherapy department, School of Rehabilitation Sciences, Madadkaran St., Shahnazari St., Madar squ., Mirdamad St.

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**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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**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

Physiotherapy

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**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Sarrafzadeh Javad

**Position**

Associate professor

**Latest degree**

Ph.D.

**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**