

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Investigation of the effect and comparison of two high-power laser treatment protocols for the improvement of clinical symptoms in patients with painful points in the upper trapezius muscle: a randomized clinical trial

#### Protocol summary

##### Study aim

Reduce patient pain

##### Design

This study will be conducted in Amin Hospital of Isfahan and it is triple-blind. After selecting the samples, the participants in the study, the researcher and the analyst, are not aware of the allocation method, and the treatment is performed by the clinical caregiver who is aware of the allocation method, and the data collection is also done by them.

##### Settings and conduct

This study will be conducted in Amin Hospital of Isfahan and it is triple-blind.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age more than 18 years, Visual analog scale greater than 5 points, Duration of pain more than a month, Patient satisfaction to participate in the study.

Exclusion Criteria: A history of cervical spine fracture and spine-related problems, Neck surgery, myelopathy or radiculopathy of the neck, Patients with perceptual disorders and pain diagnosis, Patients with myopathy and polyneuropathy, Mental illnesses or cognitive disorders, Receiving narcotics and coronet orally or intravenously, pregnancy and Blood clotting problem

##### Intervention groups

Group A: In addition to standard and routine treatment. He receives 4 sessions (two sessions per week) of high-power laser (wavelength 910 nm and power of one watt as a pulse and DUTY CYCLE 80% and frequency 60 kHz).  
Group B: In addition to standard and routine treatment. He receives 4 sessions (two sessions per week) of high power laser (wavelength 1064 nm and power of one watt as a pulse and DUTY CYCLE 80% and frequency 60 kHz).  
Group C: Like other groups, they receive standard and routine treatment, but for the purpose of checking the real or psychological effect of the laser, the laser is

turned off and without wavelength for them is placed.

##### Main outcome variables

Reducing pain and disability in patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230324057771N1**

Registration date: **2023-04-24, 1402/02/04**

Registration timing: **prospective**

Last update: **2023-04-24, 1402/02/04**

Update count: **0**

##### Registration date

2023-04-24, 1402/02/04

##### Registrant information

##### Name

Amin Mokhtari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3651 5780

##### Email address

aminmokhtari111273@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-05, 1402/02/15

##### Expected recruitment end date

2024-05-04, 1403/02/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation of the effect and comparison of two high-power laser treatment protocols for the improvement of clinical symptoms in patients with painful points in the upper trapezius muscle: a randomized clinical trial

**Public title**

comparison of two high-power in the upper trapezius muscle

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age more than 18 years Visual analog scale greater than 5 points Duration of pain more than a month Patient satisfaction to participate in the study

**Exclusion criteria:**

A history of cervical spine fracture and spine-related problems Neck surgery, myelopathy or radiculopathy of the neck Patients with perceptual disorders and pain diagnosis Patients with myopathy and polyneuropathy Mental illnesses or cognitive disorders Receiving narcotics and coronet orally or intravenously pregnancy Blood clotting problem

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **78**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

With the easy sampling method, the referring people who are eligible to enter the study are randomly divided into three intervention, control and control groups. In this study, the classification of people is done in the form of three permutation block method. In this method, A represents the person who receives the intervention, B represents the person who is in the control group, and c represents the person in the control group. By considering the block of three, permutations are determined. Then, using the table of random numbers, we randomly select a starting point and then consider 26 numbers in rows or columns. Finally, by selecting 26 numbers from the table, the total allocation of 78 people will be divided into three groups.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

After selecting the samples, the participants in the study, the researcher and the analyst are not informed about the allocation method and the treatment is done by the clinical caregiver who is aware of the treatment method and the data collection is also done by them.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Esfahan University of Medical Sciences

**Street address**

Hazarjarib Street, Azadi Square

**City**

Esfahan

**Province**

Isfahan

**Postal code**

81746-73461

**Approval date**

2023-03-01, 1401/12/10

**Ethics committee reference number**

IR.MUI.MED.REC.1401.420

**Health conditions studied****1****Description of health condition studied**

pain in the upper trapezius muscle

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Pain reduction in the patient

**Timepoint**

before the treatment, immediately after the treatment, one month and three months after the treatment in each of the three groups

**Method of measurement**

VAS pain scale

## 2

### **Description**

Reducing disability in the patient

### **Timepoint**

before the treatment, immediately after the treatment, one month and three months after the treatment in each of the three groups

### **Method of measurement**

Shoulder Pain and Disability Index (SPADI) scale

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: In addition to standard and routine treatment. He receives 4 sessions (two sessions per week) of high power laser (wavelength 910 nm and power of one watt as pulse and 80% duty cycle and frequency 60 kHz).

#### **Category**

Treatment - Devices

### 2

#### **Description**

Intervention group: Intervention group: In addition to standard and routine treatment. He receives 4 sessions (two sessions per week) of high power laser (wavelength 1064 nm and power of one watt as a pulse and 80% DUTY CYCLE and frequency 60 kHz).

#### **Category**

Treatment - Devices

### 3

#### **Description**

Control group: Like other groups, they receive standard and routine treatment including corrective exercises and POSTURE training, but for the purpose of checking the real or psychological effect of the laser, the laser is switched off and without wavelength.

#### **Category**

Treatment - Devices

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Amin Hospital

##### **Full name of responsible person**

Babak Vahdatpour

##### **Street address**

Sanbalistan Street, Ibn Sina Street, Shahada Square

##### **City**

Esfahan

#### **Province**

Isfahan

#### **Postal code**

81486-53141

#### **Phone**

+98 31 3112 2020

#### **Email**

vahdatpour@med.mui.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Ghalamreza Asgari

##### **Street address**

Hazarjarib Street, Azadi Square

##### **City**

Esfahan

##### **Province**

Isfahan

##### **Postal code**

81746-73461

##### **Phone**

+98 31 3668 0048

##### **Email**

dean@med.mui.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Esfahan University of Medical Sciences

#### **Proportion provided by this source**

1

#### **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**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Babak Vahdatpour

##### **Position**

Professor

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Physical Medicine

**Street address**

Sanbalistan Street, Ibn Sina Street, Shahada Square

**City**

Esfahan

**Province**

Isfahan

**Postal code**

81486-53141

**Phone**

+98 31 3112 2020

**Fax****Email**

vahdatpour@med.mui.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Babak Vahdatpour

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Sanbalistan Street, Ibn Sina Street, Shahada Square

**City**

Esfahan

**Province**

Isfahan

**Postal code**

81486-53141

**Phone**

+98 31 3112 2020

**Email**

vahdatpour@med.mui.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amin Mokhtari

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Sanbalistan Street, Ibn Sina Street, Shahada Square

**City**

Esfahan

**Province**

Isfahan

**Postal code**

81486-53141

**Phone**

+98 910 497 1330

**Email**

aminmokhtari111273@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available