

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Comparison of the effects of high-intensity laser therapy versus low-level laser therapy on pain, function and range of motion in patients with sub-acute ankle sprain: A randomized controlled trial

Protocol summary

Study aim

This study aims to compare the effects of high-intensity laser therapy, low-level laser therapy and conventional therapy on pain, function and range of motion in the patients with sub-acute ankle sprain.

Design

Thirty six patients with ankle sprain are divided into three groups (high intensity and low- level laser and control) by simple randomization using a sealed envelope. The study is double blinded and the third phase.

Settings and conduct

An ankle sprain is where one or more of the ligaments of the ankle are partially or completely torn. High Intensity Laser and Low-level laser are effective in reducing pain and improving function. But there is a lack of evidence on effectiveness of these kind of lasers in ankle sprain. This study will be double blinded (patients and assessor) and will be performed in the physiotherapy clinic of the School of Rehabilitation of Tehran University of Medical Sciences-Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 30 years, grade I or II ankle sprain in the prior one to five weeks, pain intensity will be more than 4 at Numeric Pain Rating Scale, 4 common clinical tests; palpatory tenderness, anterior drawer test, talar tilt test, and squeeze test will be used to detect the ankle sprain and to exclude other ankle injuries. Exclusion criteria: Ankle sprain Grade III, history of recent surgery, trauma and fracture, congenital and acquired deformities of lower limbs, and history of Cancer or tumors.

Intervention groups

Both intervention groups will receive routine treatments including ultrasound, supervised and home exercises. One of the intervention groups will receive the high-intensity laser and the other, the low- level laser. The

control group will just receive the routine treatments and placebo laser.

Main outcome variables

The Numeric Pain Rating Scale, Foot and Ankle Ability Measure, Range of Motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210214050356N5**

Registration date: **2022-08-03, 1401/05/12**

Registration timing: **prospective**

Last update: **2022-08-03, 1401/05/12**

Update count: **0**

Registration date

2022-08-03, 1401/05/12

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of high-intensity laser therapy versus low-level laser therapy on pain, function and range of motion in patients with sub-acute ankle sprain: A randomized controlled trial

Public title

Effects of Laser in Treatment of Ankle Sprain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 30 years Grade I or II ankle sprain in the prior one to five weeks Pain intensity will be more than 4 at Numeric Pain Rating Scale 4 common clinical tests including palpatory tenderness, anterior drawer test, talar tilt test, and squeeze test will be used to detect the ankle sprain and to exclude other ankle injuries

Exclusion criteria:

Ankle sprain Grade III History of recent surgery, trauma and fracture Congenital and acquired deformities of lower limbs History of Cancer or tumors Taking Anticoagulant medication People who will not willing to participate in the study due to any reason.

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

After the initial evaluation, the patients are randomly placed in one of the three intervention 1, intervention 2 and control groups (randomization method: block of six, unit: cluster). The randomization process will be done by an independent person and each of the numbers assigned to the participants through the software (randomization tool: Random Allocation software with a block of six and equal allocation ratio for three groups), they are placed inside a sealed envelope and the patients receive this envelope from the clinic secretary who is not aware of the evaluation processes and etc.

Blinding (investigator's opinion)

Double blinded

Blinding description

As mentioned above, the study will be double-blinded. In this way, the participants do not know in which group

they are. Participants only know that laser are used for them and have no knowledge of the type of laser (high intensity, low- level, and placebo laser in the control group). The data analyzer is also unaware of which study group the data belongs to. But the therapist, who is the one applying the different lasers, assessing the outcome measures, knows the participants' groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation- Tehran University of

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Vice Chancellor for Research, 6th Floor, Central University Organization, Corner of Ghods St, Keshavarz Blvd.

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Approval date

2022-07-16, 1401/04/25

Ethics committee reference number

IR.TUMS.FNM.REC.1401.051

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

Sprain of ankle

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

Primary outcomes**1****Description**

Pain

Timepoint

Before intervention- After the last session of intervention

Method of measurement

Numeric Pain Rating Scale

2

Description

Physical function

Timepoint

Before intervention- After the last session of intervention

Method of measurement

Foot and Ankle Ability Measure

3

Description

Range of Motion

Timepoint

Before intervention- After the last session of intervention

Method of measurement

Goniometer

4

Description

Balance

Timepoint

Before intervention- After the last session of intervention

Method of measurement

Y Balance Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Group 1 (n = 12) will receive high-intensity laser with conventional therapy (Ice, Ultrasound, supervised exercise & home exercises, three sessions in a week for three weeks.

Category

Rehabilitation

2

Description

Intervention group 2: Group 2 (n = 12) will receive low-level laser with conventional therapy (Ice, Ultrasound, supervised exercise & home exercises, three sessions in a week for three weeks.

Category

Rehabilitation

3

Description

Control group: Group 3 (n = 12) will receive placebo laser and conventional therapy (Ice, Ultrasound, supervised exercise & home exercises, three sessions in a week for three weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Sara Fereydounnia

Position

Assistant Professor

Latest degree

Ph.D.

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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

Undecided - It is not yet known if there will be 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 3 months after the articles are published

To whom data/document is available

For researchers working in academic, scientific and hospital institutions

Under which criteria data/document could be used

Researchers working in the field of musculoskeletal physiotherapy and electrotherapy.

From where data/document is obtainable

Applicants for documentation can contact Dr. Sara Fereydounnia via email. S-fereydounnia@sina.tums.ac.ir

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

Once they have the necessary criteria, the information will be provided to them within a month.

Comments

