Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 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

Sara Fereydounnia

Name of organization / entity

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Iran (Islamic Republic of)

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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
Street address
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
Sara Fereydounnia
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Sponsors / Funding sources

1

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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.

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
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