

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

The comparison of %1 hydrocortisone phonophoresis with low power laser on treatment of 2nd degree ankle sprain.

Protocol summary

Summary

Ankle sprain is the most common ankle injuries and divide to three degree 1, 2, 3 or mild, moderate and severe. The aim of this study is to comparison of %1 hydrocortisone phonophoresis with low power laser on treatment of second degree (moderate) ankle sprain. This is a double blinded randomized clinical trial. 90 patients that afflicted to ankle sprain will refer to clinical of Fattemeh physiotherapy in Rafsanjan, Iran. They will be divided in to 3 equal groups randomly. Three intervention of this study are %1 hydrocortisone phonophoresis (Ultrasound, ITO Japan with %1 hydrocortisone ointment), low power laser (Ga AL AS, 810nm, 100mV) and current treatments of physiotherapy. Intensity of pain, improvement of movement and reduction of inflammation are assessed during 1st, 5th and 10th sessions. Inclusion criteria are pain in medial and lateral malleolus, inflammation of ankle. Exclusion criteria are Achilles tendon injuries, fractures and dislocations of ankle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307233220N5**

Registration date: **2013-09-13, 1392/06/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-09-13, 1392/06/22

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2013-10-08, 1392/07/16

Expected recruitment end date

2014-08-07, 1393/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of %1 hydrocortisone phonophoresis with low power laser on treatment of 2nd degree ankle sprain.

Public title

Comparison of phonophoresis and laser in the treatment of second degree ankle sprain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pain in medial and lateral malleolus; inflammation of ankle stiffness of ankle and ecchymosis around ankle. Exclusion criteria: Achilles tendon injuries; fractures and dislocations of ankle.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rafsanjan University of Medical Science

Street address

Emam Ali ave

City

Rafsanjan

Postal code

7717893591

Approval date

2013-09-01, 1392/06/10

Ethics committee reference number

273

Health conditions studied

1

Description of health condition studied

Ankle sprain

ICD-10 code

M25

ICD-10 code description

Other joint disorders, not elsewhere classified

Primary outcomes

1

Description

Pain intensity at rest

Timepoint

1st(before treatment),5th and 10th sessions

Method of measurement

by visual analogue scale (VAS)

2

Description

Inflammation around ankle

Timepoint

1st(before treatment),5th and 10th sessions

Method of measurement

by meter (cm)

3

Description

Ankle movment

Timepoint

1st(before treatment),5th and 10th sessions

Method of measurement

by goniameter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: first group will receive %1 hydrocortisone phonophoresis by ultrasound ITO .7p .1 MHZ, Japan that is apply through 1.5 w/cm² intensity, continues wave and 5 minutes per session plus %1 hydrocortisone ointment during 10 sessions around ankle.

Category

Rehabilitation

2

Description

Intervention: second group will receive low power laser (Gal AL AS, 810nm, 100mv) through 5j intensity and 5 minutes per session on the ankle.

Category

Rehabilitation

3

Description

Control: third group (current treatment) will receive infrared (10 minutes) ultrasound 1.5 w/cm², 5 minutes) and TENS (15 minutes) per session during 10 session on ankle.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Fattemieh physiotherapy clinic

Full name of responsible person

Dadallah shahimoridi

Street address

Rafsanjan moalem street 17 avenue

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Reza Derakhshan

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Emam Ali street

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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

Rafsanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

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Position

Academic member

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary**

empty