

# 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

Dadollah Shahimoridi

###### Name of organization / entity

Rafsanjan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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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/cm<sup>2</sup> 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/cm<sup>2</sup>, 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

**City**

Rafsanjan

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

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Derakhshan

**Street address**

Emam Ali street

**City**

Rafsanjan

**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**

Dadallah Shahimoridi

**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*