Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the efficacy of casting and splinting in the treatment of ligament injuries of ankle sprain

Protocol summary

Summary

This study is designed to compare two treatment modalities of the ankle sprain. This is a single center, double-blind randomized trial. One hundred and twenty patients of 18 to 60 years with grade 1 and 2 ankle sprains are enrolled, who are visited at the emergency department within 48 hours after the injury. Patients who have fractures or other injuries, or those who cannot be followed are excluded from the study. After the initial evaluation, patients are randomly divided into two groups. They pick up one of the envelopes in which two types of treatments are written. They are unaware of envelopes contents. Then, they enroll to the treatment groups of A (short leg cast) or B (short leg splint). Patients will be evaluated two and six weeks after the treatment regarding pain score, rate of swelling, and range of motion of the joint. The researcher is also unaware of the type of therapy. Treatment is done by another emergency physician and researcher only evaluates the variables and outcomes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071528941N1**
Registration date: **2017-01-30, 1395/11/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-30, 1395/11/11

Registrant information

Name

Homa Javan

Name of organization / entity

Mashhad University of Medical Sciencess

Country

Iran (Islamic Republic of)

Phone

+98 51 3841 1538

Email address

javanh931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-07-31, 1395/05/10

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of casting and splinting in the treatment of ligament injuries of ankle sprain

Public title

Difference between casting and splinting in the treatment of ankle sprain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients of 18 to 60 years old who are visited over the past 48 hours due to ankle sprain.
Exclusion criteria: Patients with fractures, multiple injuries, debilitating disease, grade 3 ligament injury or patients who are from another city or not consent to the study.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Next to the Hoveize cinema, Daneshgah Street

City

Mashhad

Postal code

91388-13944

Approval date

2016-01-20, 1394/10/30

Ethics committee reference number

ir.mums.fm.rec.1394.533

Health conditions studied

1

Description of health condition studied

Ankle sprain

ICD-10 code

S93.4

ICD-10 code description

Calcaneofibular (ligament); Deltoid (ligament); Internal collateral (ligament); Talofibular (ligament); Tibiofibular (ligament), distal

Primary outcomes

1

Description

Pain score

Timepoint

Before the intervention, two and six weeks after the intervention

Method of measurement

Visual Analogue Scale

2

Description

Ability to walking

Timepoint

Before the intervention, two and six weeks after the intervention

Method of measurement

Questionnaire

3

Description

Range of motion of ankle joint

Timepoint

Before the intervention, two and six weeks after the intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Pain score

Timepoint

Before the intervention, two and six weeks after the intervention

Method of measurement

Visual Analogue Scale

2

Description

Ability to walking

Timepoint

Before the intervention, two and six weeks after the intervention

Method of measurement

Questionnaire

3

Description

Range of motion of ankle joint

Timepoint

Before the intervention, two and six weeks after the intervention

Method of measurement

Questionnaire

Intervention groups

1

Description
Intervention group: In this group, full immobilization of ankle is done using the short leg cast. First, one layer of wibril is wrapped around the patient's leg (from the lower part of the knee to the metatarsophalangeal joint). Then, the plaster of paris (gipsoband) is soaked in water. Then, it is wrapped in several layers around the wibril and molded. The leg is protected until drying and hardening of the plaster.

Category
Treatment - Other

2

Description
Control Group: In this group, ankle is immobilized using short leg splint. A pre-prepared packs of splint is placed at the posterior part of the patient's foot (from the lower part of the knee to the metatarsophalangeal joint), after soaking in water. Then, it is rounded and closed with an elastic band.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Edalatian Emergency Department, Imam Reza Hospital

Full name of responsible person
Homa Javan

Street address
Imam Reza Square, Ibnesina Avenue

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

Street address
Next to the Hoveize cinema, Daneshgah Street

City
Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Homa Javan

Position
Resident of Emergency Medicine, MD

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Ehsan Bolvardi

Position
Assistant professor of Emergency Medicine

Other areas of specialty/work

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Person responsible for updating data

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Position
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Other areas of specialty/work

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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