

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The comparison of stability and functional treatment in ligament damaged: a randomised clinical trial.

Protocol summary

Summary

This study is a randomized clinical trial. The purpose of this study is to compare two treatment methods for patients diagnosed with acute ligament injuries. Data will be collected using investigator-made questionnaire for all patients aged between 15-45 and diagnosed with acute ligament injuries referred to the Emergency Clinic of Beheshti Hospital of Yasouj. One hundred recruited patients randomly allocated to two groups: aged 15 to 45, no experience of old treatment, or history of rheumatoid disease, getting injury less than 48 hrs, and exclusion criteria are: medical complications, and no complete adherence during study. Patients in Control group will be treated by immobilized building and patients in case group will be treated by functional treatment. Patients are followed at six-month intervals. Results of treatment are recorded at two weeks, six weeks, three months, and six months later. The variables of pain, recurrence of symptoms, functional stability, swelling, tenderness, ecchymosis, joint mobility, back to work will be evaluated by Medical students Internship under supervision of orthopedic specialist physician. Finally, the results will be compared.

General information

Acronym

treatment in ligament damaged

IRCT registration information

IRCT registration number: **IRCT201102035619N2**

Registration date: **2011-07-04, 1390/04/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-04, 1390/04/13

Registrant information

Name

Hamid Reza Ghafarian Shirazi

Name of organization / entity

Yasouj University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Yasouj University of Medical Sciences

Expected recruitment start date

2009-01-20, 1387/11/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of stability and functional treatment in ligament damaged: a randomised clinical trial.

Public title

Stability versus functional treatment in ligament damage.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : getting injury in less than 48 hr; no history of acute injury to the ankle ligaments; no experience of treatment in other clinics; No history of rheumatoid disease; Exclusion criteria : medical

complication; no complete adherence.

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yasouj University Of Medical Sciences

Street address

Faculty of Medicine

City

Yasouj

Postal code

7591854593

Approval date

2008-04-11, 1387/01/23

Ethics committee reference number

870123/5

Health conditions studied

1

Description of health condition studied

Injury of muscle and tendon at ankle and foot level

ICD-10 code

s96

ICD-10 code description

Injury of muscle and tendon at ankle and foot level

Primary outcomes

1

Description

Pain

Timepoint

first week;sixth Week, third month; sixth month

Method of measurement

standard pain scalle questioner

2

Description

Joint Mobility

Timepoint

first week;sixth Week, third month; sixth month

Method of measurement

Orthoped Physisian Opinion

3

Description

Inflation

Timepoint

first week; sixth week; first month; sixth month

Method of measurement

examination

Secondary outcomes

1

Description

Recovery time

Timepoint

1 & 6 Weeks, 3 & 6 Monthes

Method of measurement

Ortopedic Physisisan Opinion

Intervention groups

1

Description

Patiant's in control group will threat by immobilized building by cast for two weeks without -weight bearing and then physical therapy program begins. patients in trial group will threat by functional treatment. in this method of treatment, for the first 48 hours, patient's leg bandages, elastic wrist and then let functional brace with weight bearing , also physical therapy begins.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Martyr Mofateh Speciality clinic of Yasouj

Full name of responsible person

Dr Hamid Reza Mohamadi

Street address

Yasouj, Martyr Mofateh Street

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University Of Medical Sciences

Full name of responsible person

Dr Mohamad Zoladl

Street address

Research Deputy, Yasouj University Of Medical Sciences

City

Yasouj

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yasouj 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

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Full name of responsible person

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Position

Biostatistics PhD

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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