

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 1223 4850

##### Email address

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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 Physisian 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**

Yasouj University of Medical Sciences

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Hamid Reza Ghafarian Shirazi

**Position**

Biostatistics PhD

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## Person responsible for scientific

## inquiries

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## Person responsible for updating data

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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*