

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The result of comparing cast and bondage methods treatment of ankle sprain in the patients

#### Protocol summary

##### Study aim

Comparison of the results of cast and bandage treatment methods on ankle sprain in patients

##### Design

Two arm parallel group randomised trial with non-blinded with control group

##### Settings and conduct

This study was designed as a clinical trial. After the approval of the plan in the research council of the university and after coordination with the emergency department, patients who referred to the Emergency Hospital of Poursina, who need medical treatment with ankle sprain, should enter the study within 6 months. Patients are examined and divided into two types according to severity of injury. In this study, sampling would be gradual sampling. Patients then, given that Types 1 and 2 are different, Typing 1 is outside the study and patients are classified according of clanton and mcgarvey to the severity of the ligaments to the cluster type 2, group 2, type A, which is intended in this study.

##### Participants/Inclusion and exclusion criteria

Include: Type II-unstable ankle with positive anterior drawer test or positive talar tilt test or both Group2-Athlete or high demand patient Type A; negative radiographic stress test ;functional treatment Exclude: Patients with neuropathy (diabetes or other causes). Patients with damaged organ varices Diabetes History of ankle fracture Previous history of sprain and surgery Patients requiring operation Low demand Patients with weakness lower limb that increase effected on the other side

##### Intervention groups

Patients who type 2 in group 2, type A, are included in the study and randomly divided into two groups. For first group bandage is performed and for the second group short cast is performed.

##### Main outcome variables

Visual Analog Scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190529043760N1**

Registration date: **2019-06-12, 1398/03/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-06-12, 1398/03/22**

Update count: **0**

##### Registration date

2019-06-12, 1398/03/22

##### Registrant information

##### Name

Kamran Asadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3323 2200

##### Email address

kamran\_asadi@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2019-07-22, 1398/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The result of comparing cast and bondage methods treatment of ankle sprain in the patients

#### **Public title**

Study of cast and bondage methods treatment of ankle sprain in the patients

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Type II-unstable ankle with positive anterior drawer test or positive talar tilt test or both Group 2- Athlete or high demand patient Type A; negative radiographic stress test ;functional treatment

##### **Exclusion criteria:**

Patients with neuropathy (diabetes or other causes).  
Patients with damaged organ varices Diabetes History of ankle fracture Previous history of sprain and surgery  
Patients requiring operation Low demand Patients with weakness lower limb that increase effected on the other side

#### **Age**

No age limit

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **78**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

The sampling method of this study was gradual in the patients' group so that who referred to the orthopedic department of Poursina Hospital, if they had the criteria and conditions for entering the study, and they had satisfied in the research based on four random blocks, according to The sample size will be about 40 blocks. Firstly, in a envelope and stamped in the orthopedic research center, it will be determined that randomization is assigned to two groups A (cast) and B (bandage). The research group will not be of any benefit in selecting the samples.

#### **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**

Ethics committee of guilan University of Medical Sciences

##### **Street address**

Research and Technology Center of Guilan University of Medical Sciences, in front of 17th shahrivar hospital, Namjoo Street, shahid Siadati St

##### **City**

Rasht

##### **Province**

Guilan

##### **Postal code**

4144666949

##### **Approval date**

2019-04-13, 1398/01/24

##### **Ethics committee reference number**

ir.gums.rec.1398.025

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

ankle sprain

##### **ICD-10 code**

S93.4

##### **ICD-10 code description**

Sprain of ankle

### **Primary outcomes**

#### **1**

##### **Description**

pain

##### **Timepoint**

3,6,12 weeks

##### **Method of measurement**

visual analogue scale

### **Secondary outcomes**

#### **1**

##### **Description**

Movement restriction

##### **Timepoint**

3,6,12 weeks

##### **Method of measurement**

physical exam

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: The ankle plastering for 3 weeks

##### **Category**

Treatment - Devices

## 2

### Description

Control group: the ankle bandage for 3 weeks

### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Poursina Hospital

##### Full name of responsible person

Kamran Asadi

##### Street address

Poursina Hospital, Namjoo St, Rasht

##### City

Rasht

##### Province

Guilan

##### Postal code

41937-13194

##### Phone

+98 13 3332 2444

##### Fax

+98 13 3333 9842

##### Email

poursina\_pr@yahoo.com

##### Web page address

<http://www.gums.ac.ir/poursina/Home>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Shademan Nemati

##### Street address

shahid Siadati St., Namjoo Ave.,

##### City

Rasht

##### Province

Guilan

##### Postal code

41937-13194

##### Phone

+98 13 3333 5821

##### Fax

+98 13 3333 6395

##### Email

research@gums.ac.ir

##### Web page address

<http://www.gums.ac.ir/research/default-303.aspx>

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Rasht University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

Public

##### Domestic or foreign origin

Domestic

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Kamran Asadi

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Orthopedics

##### Street address

Poursina Hospital, Namjoo Ave.

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##### Province

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##### Phone

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Rasht University of Medical Sciences

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Guilan

**Postal code**

4193713194

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available