

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

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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

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shahid Siadati St., Namjoo Ave.,

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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

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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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