

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of effects of ankle kinesiотaping, soft ankle orthosis and semi-rigid ankle orthosis on balance in patients with chronic ankle instability

Protocol summary

Study aim

Evaluation and comparison of Chronic ankle instability patient with using Star Excursion Balance Test, Single Leg Stance Test, Single Leg Hop Test before and after treatment

Design

In this study, 60 subjects with Chronic ankle instability were selected by convenience sampling method and randomly divided into 4 groups.

Settings and conduct

Individuals in each group are evaluated once before starting the study and once after completion of the treatment using balance tests. The participants are evaluated by an assessor and interventions are done by another person. The participants are evaluated at the Faculty of Rehabilitation Sciences Clinic

Participants/Inclusion and exclusion criteria

Inclusion criteria The history of at least one significant ankle sprain-The primary ankle sprain should have occurred at least 12 months before the study, accompanied by inflammatory symptoms (pain, swelling, etc.) and caused at least one day interruption in the physical activity of the individual exclusion criteria Surgical history of musculoskeletal structure in both lower limbs. The history of fracture in each of the lower limbs that needs to be reconstructed Acute injury to musculoskeletal structures

Intervention groups

participants was divided in 4 group first group received soft orthosis second group received semi-rigid orthosis third group received KinesioTape fourth group received no intervention

Main outcome variables

static balance; dynamic balance; function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037576N3**

Registration date: **2018-07-03, 1397/04/12**

Registration timing: **prospective**

Last update: **2018-07-03, 1397/04/12**

Update count: **0**

Registration date

2018-07-03, 1397/04/12

Registrant information

Name

Mohammad Hadadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 1551

Email address

hadadim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-06, 1397/05/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of ankle kinesiotopeing, soft ankle orthosis and semi-rigid ankle orthosis on balance in patients with chronic ankle instability

Public title

Evaluation of effect of orthoses on chronic ankle instability

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The history of at least one significant ankle sprain-The primary ankle sprain should have occurred at least 12 months before the study, accompanied by inflammatory symptoms (pain, swelling, etc.) and caused at least one day interruption in the physical activity of the individual The last sprain should have occurred three months before the study. Reporting the previous ankle injury, ankle giving way (at least 2 cases in 6 months before the study) recurrent ankle sprain (2 cases of sprain or more) and feeling of instability in the ankle jointIn the assessments done A score of less than 90% in the daily activities section and a score of less than 80% in the sports activities section of the FAAM questionnaire A score of less than 24 from the CAIT questionnaire. age range of 18 to 45 years

Exclusion criteria:

Surgical history of musculoskeletal structure in both lower limbs. The history of fracture in each of the lower limbs that needs to be reconstructed Acute injury to musculoskeletal structures of the other lower limb joints over the past 3 months, which has impaired individual function

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization is used to randomize the allocation of individuals to groups

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be evaluated by someone other than the therapist and the evaluator does not have any information on patients grouping

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz university of medical sciences ethics committee

Street address

School of Rehabilitation- Abiverdi1- Chamran Blvd

City

Shiraz

Province

Fars

Postal code

71345-1733

Approval date

2018-05-09, 1397/02/19

Ethics committee reference number

IR.SUMS.REC.1397.150

Health conditions studied

1

Description of health condition studied

Chronic Ankle Instability

ICD-10 code

M25.37

ICD-10 code description

Other instability, ankle and foot

Primary outcomes

1

Description

Assessment the dynamic balance

Timepoint

before the onset and after the completion of therapeutic sessions

Method of measurement

modified star excursion balance test,

2

Description

Assessment the Static balance

Timepoint

before the onset and after the completion of therapeutic session

Method of measurement

single leg stance test

3

Description

Assessment the function

Timepoint

before the onset and after the completion of therapeutic session

Method of measurement

single leg hop test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: soft orthosis- a neoprene ankle support that wear for 4 weeks

Category

Treatment - Devices

2**Description**

Intervention group: semi-rigid orthosis- an ankle support with thermoplastic support that wear for 4 weeks

Category

Treatment - Devices

3**Description**

Intervention group: Kinesio Tape- in this group, ankle taping is done with using Kinesio Tape for 4 weeks

Category

Treatment - Devices

4**Description**

Control group: no treatment

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hadadi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

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Grant name

Vice-Chancellery for Research and Technology of Shiraz University of Medical Sciences

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hadadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

orthotics and prosthetics

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Person responsible for scientific inquiries

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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