

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effects of combined mechanism ankle support, neoprene ankle support and custom made insole on dynamic balance of patient with chronic ankle instability

Protocol summary

Study aim

Comparison of the effect of combined ankle support, neoprene ankle support and custom made insole on dynamic balance of individuals with ankle instability

Design

Quasi-experimental and cross-sectional In this study 22 eligible subjects with chronic ankle instability would be selected based on convenience sampling method and the immediate effect of orthoses on their balance would be evaluated

Settings and conduct

In this study, by using a star excursion balance test in a biomechanical laboratory, the effect of three types of orthoses on the balance of patients with chronic ankle instability would be evaluated. In this regard, the subjects would be investigated in 4 conditions; without orthosis, with combined ankle support, with neoprene ankle support and with custom made insole. The order of evaluation of orthoses would be selected randomly.

Participants/Inclusion and exclusion criteria

Inclusion criteria -at least one significant ankle sprain - continuing feeling of instability and/or ankle giving way - acquire a score of <24 from Cumberland Ankle Instability Tool acquire a score less than 90% of possible score from activities of daily living subscale, of Foot and Ankle Ability Measure (FAAM) acquire a score less than 80% of possible score from sport subscale of Foot and Ankle Ability Measure (FAAM) Exclusion criteria -History of diseases that disturb balance -Taking medications that affect the balance -History of musculoskeletal disorders - history of fracture in lower extremity or acute injury to musculoskeletal -structures of the lower extremity - history of previous surgeries to the musculoskeletal structures of the lower extremity

Intervention groups

Combined ankle support, Neoprene ankle support and Custom made insole

Main outcome variables

Dynamic balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037576N1**

Registration date: **2018-01-22, 1396/11/02**

Registration timing: **retrospective**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

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

2017-10-23, 1396/08/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison the effects of combined mechanism ankle support, neoprene ankle support and custom made insole on dynamic balance of patient with chronic ankle instability

Public title
Comparison the effect of ankle orthoses on balance of patient with ankle instability

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 at least one significant ankle sprain continuing feeling of instability and/or ankle giving way acquire a score of <24 from Cumberland Ankle Instability Tool acquire a score less than 90% of possible score from activities of daily living subscale, of Foot and Ankle Ability Measure (FAAM) acquire a score less than 80% of possible score from sport subscale of Foot and Ankle Ability Measure (FAAM)
Exclusion criteria:
 History of diseases that disturb balance Taking medications that affect the balance History of musculoskeletal disorders history of fracture in lower extremity or acute injury in musculoskeletal structures of the lower extremity history of previous surgeries in the musculoskeletal structures of the lower extremity

Age
From **18 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
 Target sample size: **22**
 Actual sample size reached: **22**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

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
2017-10-18, 1396/07/26

Ethics committee reference number
IR.SUMS.REC.1396.113

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
Dynamic balance with star excursion balance test

Timepoint
Before and after wearing the orthoses

Method of measurement
With star excursion balance test

Secondary outcomes
empty

Intervention groups

1

Description
Intervention group: In this study, each person would be evaluated in four condition; without orthosis (as control), with combined ankle support, neoprene ankle support and custom made insole.

Category
Treatment - Devices

2

Description

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz university of medical sciences

Full name of responsible person

Mohammad Hadadi

Street address

School of Rehabilitation- Abiverdi1- Chamran Blvd

City

Shiraz

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Phone

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Email

hadadim@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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City

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Grant name

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

Rehabilitation management

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Person responsible for scientific 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.

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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