Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hadadi
Street address
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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

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Person responsible for updating data

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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