Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

the effect of pneumatic ankle orthosis in balance on subjects with functional ankle instability

Protocol summary

Study aim
Effect of pneumatic ankle orthosis in balance on subjects with with functional ankle instability

Design
before-after clinical trial Sampling will be done among the volunteers referring to the medical and rehabilitation centers of Isfahan in the fall of 1998 who met the inclusion criteria. The study was performed on 20 patients with functional ankle instability. Participants were evaluated before and after using a pneumatic ankle support, so that each volunteer was given static and dynamic balance tests at least five times before using orthoses and at least five times after using them.

Settings and conduct
This study will be performed in the Musculoskeletal Research Center of Isfahan University of Medical Sciences. The Qualysis 3D motion analysis system will be used to collect walking information, which includes seven 100 Hz infrared cameras and a Kistler force plate. Also used is Xiamen Huakang Orthopedic Pneumatic Ankle Orthopedic with ankle strap, safety guard, air pump and air chamber in which the size of the air inside will be adjusted according to the patient's power.

Participants/Inclusion and exclusion criteria
A history of unilateral ankle sprains at least 12 months before the study (last 1-3 years) that resulted in pain, swelling, and loss of function

Intervention groups
subjects with with functional ankle instability are evaluating before and after intervention. Intervention includes the use of pneumatic orthosis of the ankle with ankle strap, protective guard, air pump and air chamber in which the amount of air inside is adjusted based on the patient's power.

Main outcome variables
balance,

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200516047459N2**
Registration date: **2020-10-11, 1399/07/20**
Registration timing: **retrospective**

Last update: **2020-10-11, 1399/07/20**
Update count: **0**

Registration date
2020-10-11, 1399/07/20

Registrant information

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Masoud Rafiaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-02-19, 1398/11/30

Actual recruitment start date
2019-09-23, 1398/07/01

Actual recruitment end date
2020-02-19, 1398/11/30

Trial completion date
2020-03-10, 1398/12/20

Scientific title

the effect of pneumatic ankle orthosis in balance on subjects with functional ankle instability

Public title
Effect of ankle support on ankle instability
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
range of age between 18 to 35 History of unilateral ankle sprain, at least 12 months before the study History of at least 2 unilateral ankle sprains or sprains in the last 12 months Obtaining a score of 90% or less on the daily activity scale and a score of 80% or less on the sports scale in the Foot and Ankle Ability Questionnaire
Exclusion criteria:
Any history of lower limb fractures or surgery or other musculoskeletal disorders such as low back pain Receive any other rehabilitation treatment while studying Take sedatives for the past 48 hours and take any medications that cause imbalance or cognitive changes
Age
From **18 years** old to **35 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **20**
Actual sample size reached: **20**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Isfahan University of Medical Sciences
Street address
Hezarjerib
City
Isfahan
Province
Isfehan
Postal code
8193854996
Approval date
2019-09-01, 1398/06/10
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.091

Health conditions studied

1

Description of health condition studied
Functional ankle instability
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
balance
Timepoint
before and 2 hours after intervention
Method of measurement
force plate

Secondary outcomes

empty

Intervention groups

1

Description
In this study, pneumatic ankle orthosis from Xiamen Huakang Orthopedic Company with ankle strap, protection guard, air pump and air chamber that the size of the air inside was adjusted according to the patient's power will be used.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
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Sponsors / Funding sources

1

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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
Esfahan 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
Esfahan University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Effect of ankle orthoses on subjects with functional ankle instability
When the data will become available and for how long
12 month
To whom data/document is available
Masoud Rafiaei
Under which criteria data/document could be used
For using in other literature
From where data/document is obtainable
First author
What processes are involved for a request to access data/document
send e-mail to author
Comments