Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The Effects of Neoprene Ankle Support with figure 8 Straps on Rearfoot and Ankle Kinematic in people with Chronic Ankle Sprain

Protocol summary

Study aim
The effects of Ankle Support on Ankle Kinematics in people with Ankle Sprain

Design
This is a Quasi-Experimental Study with Prospective directions. The Sample included 10 Healthy Individuals and 10 Individuals with Chronic Ankle Sprains

Settings and conduct
Given the type of study, the first stage of this study is Cross Sectional. So that the Kinematic of the Ankle and Rearfoot in both groups of Healthy and Chronic Ankle Sprains will be recorded and then compared. in the second phase of this study, the effects of the strapping (With 5 random modes) on the Kinematic of the Ankle and Rearfoot in Healthy subjects and then in those with Chronic Ankle Sprains will be examined. This RCT will be performed at the Muscloskeletal Research Center at Isfahan University of Medical Science.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:The existence of Mechanical Instability, Frequent Ankle Sprain at least 2 times in the last 12 months Exclusion Criteria:Initial Ankle Sprain and Ankle giving a way during the last 6 weeks, history of Fracture or Ankle Surgery, Lower Extremity pain

Intervention groups
This study investigates the effect of one intervention (how to fasten the Neoprene Ankle Support Straps) on Ankle kinematics and Rearfoot in healthy individuals and then in individuals with chronic ankle sprain. The method of this study is before-afte.5 conditions including no strap and 3 types of straping will be investigated in a randomised order.the same intervention with the same method will be conducted in a group of individuals with chronic ankle sprain to undrestand the common effect of impairment and intervention together.

Main outcome variables
The Range of Motion of the Ankle and Rearfoot in 3 Planes of Motion, the maximum Range of Motion of the Ankle and Rearfoot.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200315046780N1**
Registration date: **2020-07-16, 1399/04/26**
Registration timing: **retrospective**

Last update: **2020-07-16, 1399/04/26**
Update count: **0**

Registration date
2020-07-16, 1399/04/26

Registrant information
Name
Elham Ranjbar sepoleh
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
2019-12-08, 1398/09/17
Expected recruitment end date
2020-03-02, 1398/12/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The Effects of Neoprene Ankle Support with figure 8 Straps on Rearfoot and Ankle Kinematic in people with Chronic Ankle Sprain

Public title

The Effect of Ankle Support on walking pattern in people with frequent Ankle Sprain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A History of at least one Ankle Sprain in the past three months that has resulted in Pain, Swelling, Stiffness and prevent People from participating in Sports, Recreation or other Activities for at least three weeks The existence of Mechanical Instability Frequent Ankle Sprain at least 2 times in the last 12 months Low to medium Ankle Sprain Chronic Unilateral Ankle Sprain and no injury to the opposite side There are at least 5 reports of Ankle giving a way and tendency to Ankle giving a way during Exercise.

Exclusion criteria:

Initial Ankle Sprain and Ankle giving a way during the last 6 weeks History of Fracture or Ankle Surgery, Lower Extremity pain not related to Ankle Sprain Extreme Ankle Sprain Pain in the lower Limb that is not related to Ankle Sprain Balance problems, other Orthopedic diseases, Systemic and Neurological diseases such as Diabetes, MS, Stroke and Cerebral Palsy Recent participation in a Rehabilitation program over the past month History of using Neoprene Ankle Support over the past month Over 90% score in Foot and Ankle Disability Index questionnaire

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

This study investigates the effect of one intervention (how to fasten the Neoprene Ankle Support straps) on ankle kinematics and rearfoot in healthy individuals and then in individuals with chronic ankle sprain. The method of this study is before-afte.4 conditions including no strap and 3 types of straping will be investigated in a randomised order.the same intervention with the same method will be conducted in a group of individuals with chronic ankle sprain to undrestand the common effect of impairment and intervention together.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Science, Hezar Jerib St

City

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Province

Isfehan

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81745164

Approval date

2019-11-08, 1398/08/17

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.433

Health conditions studied

1

Description of health condition studied

Chronic Ankle Sprain

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

Primary outcomes

1

Description

Rearfoot and Ankle Kinematic

Timepoint

Measurement of the Ankle and Rearfoot Kinematic at the beginning of the study (without Intervention or without the use of Neoprene Ankle Support) with 7 repetitions and then the Kinematic of Ankle and Rearfoot measured with using the Neoprene Ankle Support.

Method of measurement

Using QTM software, inematic data is recorded, then we use Visual-3D software for kinematic analysis and data modeling and then statistical analysis is performed with SPSS software.

Secondary outcomes

empty

Intervention groups

1

Description
This study investigates the effect of one intervention (how to fasten the Neoprene Ankle Support straps) on ankle kinematics and rearfoot in healthy individuals and then in individuals with chronic ankle sprain. The method of this study is before-afte.4 conditions including no strap and 3 types of straping (using Neoprene Ankle Support with equal force of straps, using Neoprene Ankle Support with Evertor force of straps and using Neoprene Ankle Support with Invertor force of straps) will be investigated in a randomised order.the same intervention with the same method will be conducted in a group of individuals with chronic ankle sprain to undrestand the common effect of impairment and intervention together.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan University of Medical Science, School of Rehabilitation Science, Muscloskeletal Research Cen

Full name of responsible person
Elham Ranjbar Sehpole

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Muscloskeletal Research Center, School of Rehabilitation Science, western door of the Esfahan University of Medical Science, Sofe Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Vice-Chancellery for Research and Technology of 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

Full name of responsible person
Elham Ranjbar Sehpole

Position
Masters Student

Latest degree
Bachelor

Other areas of specialty/work
Orthosis and Prosthesis

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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