

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 Musculoskeletal 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-after. 5 conditions including no strap and 3 types of strapping 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 understand 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

Country

Iran (Islamic Republic of)

Phone

+98 31 3434 0190

Email address

inspiration_r11@yahoo.com

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-after.4 conditions including no strap and 3 types of strapping 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 understand 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

Esfahan

Province

Isfahan

Postal code

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, kinematic 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-after. 4 conditions including no strap and 3 types of strapping (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 understand 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, Musculoskeletal Research Center

Full name of responsible person

Elham Ranjbar Sehpole

Street address

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

City

Esfahan

Province

Isfahan

Postal code

81174673461

Phone

+98 31 3792 5229

Fax

+98 31 3668 7270

Email

muigaitlab@gmail.com

Web page address

<https://msrcenter.mui.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

dr.Shaghayegh Haghjoy Javanmard

Street address

Vice-Chancellery for Research and Technology, number 4 Bldg, Esfahan University of Medical

Science, Hezar Jerib St

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Web page address

<https://research.mui.ac.ir/>

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

Street address

in front of Motamed Clinic, Sartip Cross, Taleghani Ave

City

Esfahan

Province

Isfahan

Postal code

8136835133

Phone

+98 31 3434 0190

Email

inspiration_r11@yahoo.com

Person responsible for scientific 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

Street address

in front of Motamed Clinic, Sartip Cross, Taleghani Ave

City

Esfahan

Province

Isfahan

Postal code

8136835133

Phone

+98 31 3434 0190

Email

inspiration_r11@yahoo.com

Person responsible for updating data

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

Street address

in front of Motamed Clinic, Sartip Cross, Taleghani Ave

City

Esfahan

Province

Isfahan

Postal code

8136835133

Phone

+98 31 3434 0190

Email

inspiration_r11@yahoo.com

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