

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Investigation of long term effect of Ankle Balance Taping method on balance and function of patients with chronic ankle instability

Protocol summary

Study aim

Investigating the long term effects of ABT procedure on balance and functional status of a patient who suffer from chronic ankle instability

Design

Randomized Clinical trial with stratified randomization, Including two parallel interventional groups, Double blind

Settings and conduct

After screening CAI patients referred to medical centers affiliated to Shiraz University of Medical Sciences and obtaining informed consent, patients would be evaluated and then randomly assigned to two treatment groups and it will be done in the Faculty of Rehabilitation Sciences of Shiraz University of Medical Sciences. The evaluations will be repeated after the end of the treatment. Assessors will not know how patients are assigned to groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: History of sever ankle sprain at least once: History of emptying and twisting again and feeling of instability in the injured ankle: CAIT score equal to or less than 24: Daily activity scale equal to or less than 90% according to FAAM questionnaire: Exercise activity scale equal to or less than 80% according to FAAM questionnaire Exclusion criteria: History of musculoskeletal surgery in each lower limb: History of lower limb fractures which need realignment: Acute musculoskeletal injury of other lower limb joints in last three month which affect joint stability and function : History of neurological disease and ocular and vestibular disorder or any event that is effective on balance : Sensitivity symptoms which are related to taping like skin redness: Pregnancy: Professional athlete

Intervention groups

We have three groups include kinsiotape group and sham group and control group. in first group we apply ABT for 4 weeks on every other day and in second group we apply tapes but without stretch and we have no intervene in third group

Main outcome variables

Static balance and dynamic balance and function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200909048671N1**

Registration date: **2020-10-26, 1399/08/05**

Registration timing: **prospective**

Last update: **2020-10-26, 1399/08/05**

Update count: **0**

Registration date

2020-10-26, 1399/08/05

Registrant information

Name

Moslem Yousefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3234 2079

Email address

moslemyousefi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of long term effect of Ankle Balance Taping method on balance and function of patients with chronic ankle instability

Public title

Investigation of effect of Ankle Balance Taping on chronic ankle instability

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

A history of at least one significant ankle sprain: The initial sprain must have occurred at least 12 months prior to the study enrolment A history of the previously injured ankle joint 'giving way', and/or recurrent sprain and/or 'feelings of instability': participants should report at least 2 episodes of 'giving way' in the 6 months prior to the study enrolment. Cumberland Ankle Instability Tool (CAIT): score of equal or less than 24 Foot and Ankle Ability Measure (FAAM): ADL scale < 90%; Sport scale < 80%

Exclusion criteria:

A history of previous surgeries to the musculoskeletal structures (ie, bones, joint structures and nerves) in either lower extremity A history of a fracture in either lower extremity requiring realignment Acute injury to the musculoskeletal structures of other joints of the lower extremity in the previous 3 months, which impacted joint integrity and function (ie, sprains, fractures) resulting in at least 1 interrupted day of desired physical activity No history of neurological disease, vestibular or visual disturbance, or any other pathology that have negative effect on balance Taping side effects such as skin redness Being professional athlete

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients after compliance with inclusion and exclusion criteria and after signing the consent form : they consciously enter the study and they divided into three groups : In order to randomly assign individuals to three groups the permutation block randomized method will be used hexagonal blocks.

Blinding (investigator's opinion)

Double blinded

Blinding description

The outcome assessor is not aware of the interventions performed on patients also, the data analyzer does not know about the intervention groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Committee on Ethics in Biomedical Research

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Sheikh Abivardi 1, Chamran Blvd., Shiraz

City

shiraz

Province

Fars

Postal code

33669-71947

Approval date

2020-05-20, 1399/02/31

Ethics committee reference number

IR.SUMS.REHAB.REC.1399.016

Health conditions studied**1****Description of health condition studied**

Chronic Ankle Instability

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

Primary outcomes**1****Description**

Dynamic balance

Timepoint

Initiation of treatment, immediately after and one month after the end of the intervention

Method of measurement

Modified star excursion balance test(mSEBT)

2**Description**

Static balance

Timepoint

Initiation of treatment, immediately after and one month

after the end of the intervention

Method of measurement

Single leg stance

3

Description

Function

Timepoint

Initiation of treatment, immediately after and one month after the end of the intervention

Method of measurement

Single leg hop

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Kinesio type group: People in this group are treated with Ankle Balance Taping for four weeks at intervals of one day. Sham Group: This intervention is inductive. In this method, we use tape without applying tension to the person. Control group: This group of patients do not receive any treatment and are evaluated only like other groups before, immediately after and one month after the treatment interventions of other groups.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

medical centers affiliated to shiraz university of medical sciences

Full name of responsible person

samane ebrahimi

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Abiverdi 1 Street, 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

Abbas Rezaianzadeh

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Deputy of Research and Technology, 7th Floor, Central Building of Shiraz University of Medical Sciences, Zand St.

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Grant name

Vice chancellor of research of Shiraz University of Medical Sciences

Grant code / Reference number

99-01-06-22602

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

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

Shiraz University of Medical Sciences

Full name of responsible person

Moslem Yousefi

Position

Bachelor student in Physical Therapy

Latest degree

A Level or less

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Name of organization / entity

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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

Not applicable

Title and more details about the data/document

All data except personal information would be available.

When the data will become available and for how long

The start of the access period is 6 months after the acceptance of the article.

To whom data/document is available

In addition to the principal researcher and the supervisor of the project, upon request, access to information can be reviewed by the Ethics Committee.

Under which criteria data/document could be used

Researchers can use data for advanced analyses or for meta analysis studies.

From where data/document is obtainable

Dr. Samaneh Ebrahimi, Shiraz, Chamran Blv., Sheikh Abivardi 1 ave., School of Rehabilitation Sciences, Mobile:09173070211, E-mail:EbrahimiS@Sums.ac.ir

What processes are involved for a request to access data/document

After 6 months from article acceptance, while announcing a written request to the executor of the project to receive information and a precise explanation about how to use the information, an official letter is also requested to obtain permission from the ethics committee to obtain a license, and if the ethics committee approves, emphasizing the confidentiality of the information, the requested information will be provided to the applicant.

Comments