

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the effect of fibular repositioning taping technique on balance in patients with chronic ankle instability

Protocol summary

Study aim

Evaluation of effect of fibular repositioning taping technique on balance in patients with chronic ankle instability

Design

a concealed, randomized, single blinded clinical trial including 3 groups (amongst Sham and control groups) with a parallel group design.

Settings and conduct

Therapeutic groups are treated for two weeks, three times a week. Assessments are performed once before the onset and once after the completion of treatment sessions in all three groups. the evaluator does not have any information on the patients grouping . All stages of assessment and treatment will be carried out at the clinic of the Faculty of Rehabilitation Sciences of Shiraz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Participants: male and female with chronic ankle instability inclusion criteria: The history of at least one significant ankle sprain, Reporting the previous ankle injury, ankle giving way, recurrent ankle sprain, feeling of instability in the ankle joint, a score of less than 90% in the daily activities section and a score of less than 80% in the sports activities section of the FAAM questionnaire and also a score of less than 24 from the CAIT questionnaire. ; Non-entry criteria: Surgical history of musculoskeletal structure in both lower limbs, the history of fracture in each of the lower limbs that needs to be reconstructed, acute injury to musculoskeletal structures of the other lower limb joints over the past 3 months, which has impaired individual function.

Intervention groups

The subjects are divided into three groups: 1) fibular repositioning tape, 2) the sham taping (taping without applying stretch), 3) control group.

Main outcome variables

static balance, dynamic balance, function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171122037576N2**

Registration date: **2018-05-24, 1397/03/03**

Registration timing: **prospective**

Last update: **2018-05-24, 1397/03/03**

Update count: **0**

Registration date

2018-05-24, 1397/03/03

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

2018-07-23, 1397/05/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of fibular repositioning taping technique on balance in patients with chronic ankle instability

Public title

Evaluation of effect of taping on balance in patients with chronic ankle instability

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The history of at least one significant ankle sprain-The primary ankle sprain should have occurred at least 12 months before the study, accompanied by inflammatory symptoms (pain, swelling, etc.) and caused at least one day interruption in the physical activity of the individual-The last sprain should have occurred three months before the study. Reporting the previous ankle injury, ankle giving way (at least 2 cases in 6 months before the study), recurrent ankle sprain (2 cases of sprain or more) and feeling of instability in the ankle joint In the assessments done: - A score of less than 90% in the daily activities section and a score of less than 80% in the sports activities section of the Foot and Ankle Ability Measure (FAAM) questionnaire.- A score of less than 24 from the Cumberland Ankle Instability Tool (CAIT) questionnaire.

Exclusion criteria:

Surgical history of musculoskeletal structure in both lower limbs. The history of fracture in each of the lower limbs that needs to be reconstructed Acute injury to musculoskeletal structures of the other lower limb joints over the past 3 months, which has impaired individual function.

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked randomization is used to randomize the allocation of individuals to groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be evaluated by someone other than the therapist and the evaluator does not have any information on patients grouping.

Placebo

Used

Assignment

Parallel

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

2018-05-09, 1397/02/19

Ethics committee reference number

IR.SUMS.REC.1397.142

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

Assessment the: dynamic balance with modified star excursion balance test, Static balance with single leg stance test, function with single leg hop test

Timepoint

before the onset and after the completion of therapeutic sessions.

Method of measurement

modified star excursion balance test, single leg stance test, single leg hop test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: fibular repositioning taping

Category

Treatment - Devices

2

Description

Intervention group: Sham taping

Category

Placebo

3

Description

Control group: receive no treatment

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

City

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Email

hadadim@sums.ac.ir

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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City

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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

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

Mohammad Hadadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

Contact

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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