

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effects of prophylactic ankle supports on electromyographic activity of selected muscles, ground reaction force, balance and perception of stability during landing in female college athletes before and after fatigue

#### Protocol summary

##### Study aim

This study was performed on athletes with chronic ankle instability at both pre and post-fatigue times. The aim of this study was to determine the effect of kinesiotape and ankle braces on the electromyographic activity of selected muscles, parameters related to the vertical ground reaction force and balance in participants and compare it at both time before and after fatigue.

##### Design

Before after clinical trial (in one group), single blinded, not randomized on 15 participants.

##### Settings and conduct

Research site: Sports Rehabilitation Research Laboratory of Bu Ali Sina University Blinding: Single blinded, The data analyzer. Data coded without details such as names of individuals and intervention will be provided to the analyzer.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: More than two incidences of ankle sprains or a greater need for medical treatment of the condition, Feelings of fear or instability of the ankle function, No history of ankle or knee injury in the past 3 months, No history of surgery or fractures of the lower extremities; The non-inclusion criteria: Chronic diseases, such as patellofemoral pain syndrome.

##### Intervention groups

Intervention group 1: Intervention with kinesiotape: After the kinesiotape with basket weaving method in the ankle, the participants perform a landing maneuver. Then the Bruce fatigue protocol used to apply fatigue, and after fatigue, the landing maneuver is performed again with kinesiotape. Intervention group 2: Intervention with brace: Participants first perform the landing maneuver by wearing braces on the ankle. Then the Bruce fatigue protocol used to apply fatigue, and after fatigue, the landing maneuver is performed again with brace.

##### Main outcome variables

The electromyographic activity of selected muscles; time to stabilization; peak vertical ground reaction force; time to peak vertical ground reaction force; perceived stability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200204046368N3**

Registration date: **2021-02-02, 1399/11/14**

Registration timing: **prospective**

Last update: **2021-02-02, 1399/11/14**

Update count: **0**

##### Registration date

2021-02-02, 1399/11/14

##### Registrant information

##### Name

Zahra Raeisi

##### Name of organization / entity

Arak University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3417 3492

##### Email address

z\_raisi13@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-08, 1399/11/20

**Expected recruitment end date**

2021-02-18, 1399/11/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effects of prophylactic ankle supports on electromyographic activity of selected muscles, ground reaction force, balance and perception of stability during landing in female college athletes before and after fatigue

**Public title**

Prophylactic ankle supports and female athletes

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

More than two incidences of ankle sprains with need for medical treatment Feelings of fear and instability in ankle function A score of  $\leq 24$  in the CAIT The confirmation of CAI via anterior drawer and talar tilt tests performed by an experienced physician

**Exclusion criteria:**

Chronic diseases such as patellofemoral pain syndrome in lower extremity Any problems affecting postural control and balance History of ankle or knee injury, surgery or fractures of the lower extremities in the past 3 months Apparent foot deformities, such as flat foot or high arch

**Age**From **18 years** old to **30 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**Target sample size: **15****Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The data analyzer will not know the details of the data. The coded data will be provided to the analyzer without details such as the names of the individuals and the intervention.

**Placebo**

Not used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

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

Ethics committee in research of Bu Ali Sina uUniversity

**Street address**

Shahid Mostafa Ahmadi Roshan street

**City**

Hamedan

**Province**

Hamadan

**Postal code**

6517838695

**Approval date**

2021-01-03, 1399/10/14

**Ethics committee reference number**

IR.BASU.REC.1399.027

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

Sprain of ankle

**ICD-10 code**

S93.4

**ICD-10 code description**

Sprain of ankle

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

Electromyography of the selected muscles

**Timepoint**

Before and after fatigue

**Method of measurement**

Biomonitor ME6000

**2****Description**

Time to stabilization

**Timepoint**

Before and after fatigue

**Method of measurement**

Plantar pressure platform

**3****Description**

Ground reaction force

**Timepoint**

Before and after fatigue

**Method of measurement**

Plantar pressure platform

**4****Description**

Perceived stability

**Timepoint**

Before and after fatigue

**Method of measurement**

Questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Bruce's general fatigue protocol is used to apply fatigue. The kinesiotape in a closed basket weave pattern and lace-up ankle brace are used on the ankle. All of the participants will perform landing tasks on the test limb under the three aforementioned (with Kinesiotape, lace-up brace and without prophylactic ankle support or control) conditions before and after fatigue while wear the same type of shoes (Air Max, Nike).

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Bu-ali Sina University

**Full name of responsible person**

Ali Yalfani

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Arak University

**Full name of responsible person**

Alireza Fazlali

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Shariati street

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**Province**

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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**

Arak University

**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**

Arak University

**Full name of responsible person**

Zahra Raeisi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bu Ali-Sina University

**Full name of responsible person**

Ali Yalfani

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Rehabilitation management

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University

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Assistant professor

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**Fax****Email**

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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**

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**

Not applicable

**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

**Title and more details about the data/document**

Part of the data on the time to stabilization vertical ground reaction force can be shared.

**When the data will become available and for how long**

One year after the publication of the study results.

**To whom data/document is available**

Researchers that working in academic institutions.

**Under which criteria data/document could be used**

Some information obtained after analysis will be possible only for researcher that experts in this field.

**From where data/document is obtainable**

Zahra Raeisi

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

The information will be available one year after the results are published.

**Comments**