

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effect of a sand training on the kinetics, amplitude of muscular electrical activity and body image in individuals with pronated feet

#### Protocol summary

##### Study aim

Effect of a sand training on the kinetics, amplitude of muscular electrical activity and body image in individuals with pronated feet

##### Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

##### Settings and conduct

Subjects' familiarity with the method of testing is carried out in the health center of Mohaghegh Ardabili University, in two stages of pre-test and post-test. Installing surface electrodes on the lower extremities of the modules and performing the process of walking and running on the force plate. How to double-blind which neither the tester nor the Subject is aware of this process.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: A navicular drop of more than 10 mm, a foot posture index of greater than 10, and age range between 18-30 years old. Exclusion criteria: The presence of limb length discrepancies of more than 5 mm, muscle spasm, neuromuscular disorders, orthopedic-related diseases or any previous surgeries in the lower limbs and trunk.

##### Intervention groups

Intervention group: Pronation complication group (barefoot walking and running before and after training sessions) Control group: Pronation complication group (walking and running barefoot before and after eight weeks without intervention)

##### Main outcome variables

Electric activity of the muscle, co-contraction and ground reaction force

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191211045704N1**

Registration date: **2020-02-25, 1398/12/06**

Registration timing: **prospective**

Last update: **2020-02-25, 1398/12/06**

Update count: **0**

##### Registration date

2020-02-25, 1398/12/06

##### Registrant information

###### Name

Amir Fatollahi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 24 3582 2100

###### Email address

amir.af@student.uma.ac.ir

##### Recruitment status

**Not yet recruiting**

##### Funding source

##### Expected recruitment start date

2641-03-01, 2019/12/10

##### Expected recruitment end date

2641-05-10, 2020/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of a sand training on the kinetics, amplitude of muscular electrical activity and body image in individuals with pronated feet

##### Public title

Effect of a sand training in individuals with flat foot

### **Purpose**

Supportive

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

pronated foot male No history of surgery

#### **Exclusion criteria:**

People with knee injuries Elderly and children

### **Age**

From **18 years** old to **30 years** old

### **Gender**

Male

### **Phase**

N/A

### **Groups that have been masked**

- Participant
- Outcome assessor

### **Sample size**

Target sample size: **30**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

The block randomization method will be used to allocate study participants into experimental and control groups. Of note, participants will be blinded to group allocation. During the randomization process, a set of sealed, opaque envelopes will be used to ensure the concealment of allocation. Each envelope will be contained a card indicating to which group the subject would be allocated.

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

The participants, the main researcher and the evaluator, do not interfere in the process of data recording and analysis. The participant will not be aware of the respective group they will be allocated to. A naïve person that will not have a role in this study will be responsible for the allocation process. One examiner will determine whether a participant will be eligible for inclusion in the trial, while the other will carry out gait analyses of the eligible participants. Both examiners will be unaware of group allocation.

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Ardabil University of Medical

Sciences

#### **Street address**

Daneshgah Ave, University of Mohaghegh Ardebili

#### **City**

Ardabil

#### **Province**

Ardabil

#### **Postal code**

4551733411

#### **Approval date**

2640-07-03, 2019/04/12

#### **Ethics committee reference number**

IR.ARUMS.REC.1398.484

## **Health conditions studied**

### 1

#### **Description of health condition studied**

over pronation

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

pronated foot

#### **Timepoint**

8 week

#### **Method of measurement**

force plate Bertec and surface EMG Bio-system

## **Secondary outcomes**

### 1

#### **Description**

flat foot

#### **Timepoint**

8 week

#### **Method of measurement**

force plate Bertec and surface EMG Bio-system

## **Intervention groups**

### 1

#### **Description**

Intervention group: During the eight weeks (3 sessions per week) of the intervention, the intervention group will be performed sand running training program that is continuous jogging, striding, and bounding, galloping, short sprints. Every session will be started with a warm-up and stretching session for five minutes and will be ended with a warm-down session for five minutes. Total training duration is 50 minutes per session.

#### **Category**

Rehabilitation

## 2

### Description

Control group: The control group will not perform any exercise and will be re-evaluated after 8 weeks.

### Category

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

University of Mohaghegh Ardabili

**Full name of responsible person**

Amir Fatollahi

**Street address**

Daneshghah Ave., University of Mohaghegh Ardabili

**City**

Ardabil

**Province**

Ardabil

**Postal code**

4551733411

**Phone**

+98 24 3582 2100

**Email**

amiraf14618@gmail.com

**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Dr Abolfazl Bezaat pour

**Street address**

Daneshghah Ave., University of Mohaghegh Ardabili

**City**

Ardabil

**Province**

Ardabil

**Postal code**

4551733411

**Phone**

+98 45 3150 5649

**Email**

a.bezaatpour@yahoo.com

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Ardabil 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

AmirAli Jafarnezhadgero

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Anatomy

**Street address**

Daneshghah Ave., University of Mohaghegh Ardabili

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5619911367

**Phone**

+98 45 3150 5649

**Email**

amiralijafarnezhad@gmail.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

AmirAli Jafarnezhadgero

**Position**

Associate professor Biomechanics

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Anatomy

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amiralijafarnezhad@gmail.com

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## Person responsible for updating data

### Contact

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Ardabil University of Medical Sciences

**Full name of responsible person**

AmirAli Jafarnezhadgero

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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