

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Effect of hydrotherapy and standard physical therapy with Thera-Band in the water on kinetics and muscle activities in adult males with pronated foot

#### Protocol summary

##### Study aim

Effect of hydrotherapy and standard physical therapy with Thera-Band in the water on kinetics and muscle activities in adult males with pronated foot

##### Design

Clinical trial study with control and experimental groups, with parallel groups, double blind, randomized

##### Settings and conduct

The place of implementation of this project is University Mohaghegh Ardabili . The present study is a three-way blind type that will include the participants, main researcher and evaluator.

##### Participants/Inclusion and exclusion criteria

Adult males with pronated foot

##### Intervention groups

Forty-five adult men with pronated foot are randomly and equally assigned to three groups: control, water therapy, and resistance training with an elastic band in water.

##### Main outcome variables

Kinetic variables and muscles electrical activity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191211045704N2**

Registration date: **2023-06-01, 1402/03/11**

Registration timing: **retrospective**

Last update: **2023-06-01, 1402/03/11**

Update count: **0**

##### Registration date

2023-06-01, 1402/03/11

##### 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

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-10, 1401/10/20

##### Expected recruitment end date

2023-03-21, 1402/01/01

##### Actual recruitment start date

2023-01-10, 1401/10/20

##### Actual recruitment end date

2023-03-20, 1401/12/29

##### Trial completion date

2023-03-20, 1401/12/29

##### Scientific title

Effect of hydrotherapy and standard physical therapy with Thera-Band in the water on kinetics and muscle activities in adult males with pronated foot

##### Public title

Effect of hydrotherapy and standard physical therapy with Thera-Band in the water on biomechanics of individuals with pronated foot

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

individuals with pronated foot between the ages of 18 to 30 years navicular drop of more than 10 mm in Subjects

greater foot posture index of 10

**Exclusion criteria:**

The presence of length difference in the lower limb  
Having any specific disease

**Age**

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

**Gender**

Male

**Phase**

3

**Groups that have been masked**

- Investigator
- Outcome assessor

**Sample size**

Target sample size: **45**

Actual sample size reached: **45**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A simple randomization method will be used. In this way, the names of the individuals are written on the paper and put into the bag, then 15 individuals are selected from the bag for the control group, and in the same way, sampling is done for the two intervention groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The main researcher and the outcome assessor are not involved in the data recording and analysis process during the study to avoid bias.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

University of Mohaghegh Ardabili

**Street address**

Daneshgah Street , University of Mohaghegh Ardabili

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5619913131

**Approval date**

2022-11-07, 1401/08/16

**Ethics committee reference number**

IR.UMA.REC.1401.082

**Health conditions studied**

**1**

**Description of health condition studied**

pronated foot

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**

kinetic and muscles electrical activity

**Timepoint**

8 weeks (pre and post test)

**Method of measurement**

force plate and surface electromyography

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

intervention group 1: includes 15 adult males with pronated foot conducted the Thera-Band in the water exercise program. The Thera-Band in the water exercise program for 8 weeks with five days per week conducted for intervention group.

**Category**

Rehabilitation

**2**

**Description**

Control group: The control group did not receive any exercise program during the study period.

**Category**

Other

**3**

**Description**

intervention group 2: includes 15 adult males with pronated foot conducted the hydrotherapy. hydrotherapy exercise program for 8 weeks with five days per week conducted for intervention group.

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

University of Mohaghegh Ardabili

**Full name of responsible person**

Mohsen Baghamadi

**Street address**

Daneshghah street, Univesity of Mohaghegh Ardabili

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5619911367

**Phone**

+98 45 3351 3920

**Email**

baghamadi@uma.ac.ir

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Anatomy

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Daneshghah Ave, University if Mohaghegh Ardabili

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

The University of Mohaghegh Ardabili

**Full name of responsible person**

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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**

The University of Mohaghegh Ardabili

**Proportion provided by this source**

1

**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**

The Univesity of Mohaghegh Ardabili

**Full name of responsible person**

Mohsen Barghamadi

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

The University of Mohaghegh Ardabili

**Full name of responsible person**

Mohsen Barghamadi

**Position**

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**Latest degree**

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**Person responsible for updating data****Contact****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**

Yes - There is a plan to make this available

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

Information about the main outcome can be shared.

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

The access period starts 6 months after the results are published

### **To whom data/document is available**

It will be available for researchers in academic and scientific institutions.

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

six months after the results are published

### **From where data/document is obtainable**

Dr. Mohsen Barghamadi, Department of sport Biomechanics, University of Mohaghegh Ardabili Tel number: 09153058339 Email: barghamadi@uma.ac.ir

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

A maximum of one week through the responsible author's email.

### **Comments**