Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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Iran (Islamic Republic of)
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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
Daneshghah 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
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Sponsors / Funding sources

1

Sponsor
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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
Position
Associate professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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