

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of activation sequences of intrinsic and extrinsic foot muscles on selected foot muscles cross section area and Normalized Truncated Navicular Height in boys afflicted by flat foot

Protocol summary

Study aim

Comparison the effect of activation sequences of intrinsic and extrinsic foot muscles on selected foot muscles cross section area and Normalized Truncated Navicular Height in boys afflicted by flat foot

Design

Two groups of intrinsic and extrinsic exercises with the blinded evaluator grouped randomly based on a random numbers table. For each group minimum of 8 individuals in each group were considered.

Settings and conduct

The test protocol will be performed in Amin hospital of Isfahan city under the supervision of a rehabilitation specialist. The tests including the assessment of the cross-section area (CSA) of the selective foot muscles and navicular drop. The CSA will be tested by alpinon ecube 9 and navicular drop by a ruler. The evaluator will be blinded to the participants' group.

Participants/Inclusion and exclusion criteria

Age (10-13), sex (boys), flexible flat foot, haven't injury or surgery in the lower extremity, haven't anatomical LLD, haven't structural dorsiflexion limitation, don't use other modalities.

Intervention groups

There are two groups: intrinsic and extrinsic exercises. The intrinsic exercises group will perform short foot exercises for 6 weeks and the extrinsic group will perform superficial foot muscles strengthening for 6 weeks. Then the groups will change their exercises.

Main outcome variables

The cross-section area of selected foot muscles; navicular drop.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210818052223N1**

Registration date: **2021-09-08, 1400/06/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-08, 1400/06/17**

Update count: **0**

Registration date

2021-09-08, 1400/06/17

Registrant information

Name

jafar ketabchi

Name of organization / entity

The university of tehran

Country

Iran (Islamic Republic of)

Phone

+98 31 3458 3685

Email address

j.ketabchi@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of activation sequences of intrinsic

and extrinsic foot muscles on selected foot muscles cross section area and Normalized Truncated Navicular Height in boys afflicted by flat foot

Public title

Comparison the activation sequences of deep and superficial foot muscle on CSA and navicular drop in flat feet children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

flexible flat foot haven't structural deformity in pelvic or foot don't use insole support during the study period 10-13 age boys don't use medicine or have a special surgery

Exclusion criteria:

Structural flat foot Have a structural deformity in the pelvic or foot No willingness to enter the study use other modalities during the study

Age

From **10 years** old to **13 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **8**

Randomization (investigator's opinion)

Randomized

Randomization description

After recruiting the participants in the research, their names are chronologically written in a list. After that, each participant is allocated a number. Two groups of intrinsic and extrinsic exercises are assigned to the participants based on a random table of numbers. In this way, a number is randomly selected first, and then by the movement to one direction, the next numbers are selected until half of the participants are selected for the intrinsic group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the evaluator (rehabilitation specialist) will not know whom she is analysing. For blind the evaluator, the groups and their exercises will remain unknown. Also the data analyst will not have access to this information. For this, the information related to the groups would be given the data analyst in a way that will not reveal the group members.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University

Street address

16th Azar St., Enghelab Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۱۷۹۳۵۸۴

Approval date

2020-09-20, 1399/06/30

Ethics committee reference number

IR.UT.SPORT.REC.1399.008

Health conditions studied

1

Description of health condition studied

flexible flat foot

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

cross section area of selective foot muscels

Timepoint

before, 6 weeks after and 12 weeks after

Method of measurement

ultrasond alpinon ecube 9

2

Description

navicular drop

Timepoint

before, 6 weeks and 12 weeks after

Method of measurement

ruller

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intrinsic foot muscle strengthening. the participants will received short foot exercises at minimum three days a week, one hour during the day in six weeks. they need only a theraband.

Category

Rehabilitation

2**Description**

Intervention group: extrinsic foot muscles strengthening. the exercises will include strengthening of gastrocnemius, soleus and tibialis anterior and posterior muscles. the participants will performe exercises at minimum three days a week, one hour during the day in six weeks. they need only a theraband.

Category

Rehabilitation

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

Corrective Exercises Centers Of Schools

Full name of responsible person

Jafar Ketabchi

Street address

Etehad Ave, Kave Ave, Isfahan, Ale Yasin School

City

Isfahan

Province

Isfahan

Postal code

8193843155

Phone

+98 31 3459 3603

Email

info@gama.ir

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

The University Of Tehran

Full name of responsible person

Foad Seidi

Street address

16th Azar St., Enghelab Sq., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

۱۴۱۷۹۳۵۸۴

Phone

+98 21 8835 1730

Email

publicrel@ut.ac.ir

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

Yes

Title of funding source

The University Of Tehran

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**

The University Of Tehran

Full name of responsible person

Jafar Ketabchi

Position

PHD Candidate

Latest degree

Master

Other areas of specialty/work

Others

Street address

No 37, Gole Roz Ave, Barazande Ave, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8193843155

Phone

+98 31 3458 3685

Email

J.ketabchi@ut.ac.ir

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

The University Of Tehran

Full name of responsible person

Jafar Ketabchi

Position

PHD Candidate

Latest degree

Master

Other areas of specialty/work

Others

Street address

No 37, Gole Roz Ave, Barazande Ave, Isfahan

City

Isfahan
Province
Isfahan
Postal code
8193843155
Phone
+98 31 3458 3685
Email
J.ketabchi@ut.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
The University Of Tehran
Full name of responsible person
Jafar Ketabchi
Position
PHD Candidate
Latest degree
Master
Other areas of specialty/work
Others
Street address
No 37, Gole Roz Ave, Barazande Ave, Isfahan
City
Isfahan
Province
Isfahan
Postal code
8193843155
Phone
+98 31 3458 3685
Email
J.ketabchi@ut.ac.ir

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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

the private information of the participants will not be published, but the assessment information will.

When the data will become available and for how long

will be accessible from 2021

To whom data/document is available

the data will be accessible as paper and phd thesis for interested individuals.

Under which criteria data/document could be used

the interested individuals that approximate the university to access the thesis or individuals that have access to the publisher.

From where data/document is obtainable

university of tehran, sport science faculty.

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

after showing student card, the student can have access to thesis.

Comments