Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 muscels and naicular drop. The CSA will be tested by alpinon ecube 9 and nacvicular 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
۱۴۱۷۹۳۵۸۴۰

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 recieved 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 muscels strengthening. the exercises will include strengthening of gastrocinemius, soleus and tibilais 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
The University Of Tehran

Full name of responsible person
Foad Seidi

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

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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

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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

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 patricipants will not 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