Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Evaluation of the effect of progressive neuromuscular training alone and combined with trigger point dry needling of peroneal muscles on functional status, postural control, and muscular activity of the lower extremity during jump-landing task in athletes with chronic ankle Instability

Protocol summary

Study aim

Evaluation of the effect of exercise therapy alone and combined with trigger point dry needling of peroneal muscles on muscular activity of the lower extremity during jump-landing task in athletes with chronic ankle Instability.

Design

Randomized, parallel group, placebo controlled trial, on 60 patients. Blocked randomization is used.

Settings and conduct

Control group: Subjects will complete progressive neuromuscular exercise, 2 sessions per week for 6 sequential weeks. Intervention group 1: The subjects will complete the same exercise program as control group.Moreover they will receive dry needling of peroneus longus and peroneus brevis trigger points, 1 session per week for 6 weeks. Intervention group 2: The subjects will complete the same exercise program as control group.Moreover they will receive placebo dry needling of peroneus longus and peroneus brevis trigger points, 1 session per week for 6 weeks.

Participants/Inclusion and exclusion criteria

Regular sport activity in soccer, volleyball or basketball, at least 3 sessions per week, each lasting at least 2 hours. Existing ankle instability according to Cumberland Ankle Instability Tools (CAIT). Clinical presentation of trigger points in peroneal muscles.

Intervention groups

Intervention group 1: exercise therapy plus dry needling Intervention group 2: exercise therapy plus placebo dry needling control group: exercise therapy alone.

Main outcome variables

Amplitude of electromyographic activity of peroneus longus, peroneus brevis, soleus, vastus medialis, gluteus medius, tibialis anterior. Onset time of peroneus longus, peroneus brevis, soleus, vastus medialis, gluteus medius, tibialis anterior.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220408054452N1**
Registration date: **2022-05-23, 1401/03/02**
Registration timing: **prospective**

Last update: **2022-05-23, 1401/03/02**
Update count: **0**

Registration date

2022-05-23, 1401/03/02

Registrant information

Name

Parsa Salemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7756 1721

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of progressive neuromuscular training alone and combined with trigger point dry needling of peroneal muscles on functional status, postural control, and muscular activity of the lower extremity during jump-landing task in athletes with chronic ankle Instability

Public title

The effect of dry needling on chronic ankle instability

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Regular sport activity in soccer, volleyball or basketball, at least 3 sessions per week, each lasting at least 2 hours A history of repeated ankle sprains along with inflammatory symptoms Existing ankle instability according to Cumberland Ankle Instability Tools (CAIT) Clinical presentation of trigger points in peroneal muscles

Exclusion criteria:

A history of musculoskeletal injury in other lower extremity joints within last 3 months leading to at least on day loss of regular activity. A history of the immune system or blood coagulation disorders, vestibular dysfunction, neurological or neurovascular conditions, or convulsion Acute inflammatory symptoms in ankle region

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects will be randomly allocated to three experimental groups using blocked randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid A'rabi St, Yaman St, Shahid Chamran highway

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Province

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Postal code

1985717443

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.991

Health conditions studied

1

Description of health condition studied

Chronic Ankle Instability

ICD-10 code

S93.4

ICD-10 code description

Sprain of ankle

Primary outcomes

1

Description

Onset time of peroneus longus, peroneus brevis, soleus, vastus medialis, gluteus medius, tibialis anterior

Timepoint

1- Before intervention 2- Immediately after the 1st session of intervention 3- After the last session of intervention 4- Three months after the end of the last session of intervention

Method of measurement

Surface electromyography device (time difference between initial foot-ground contact and onset of electromyographic activity of each muscle)

2

Description

Amplitude of electromyographic activity of peroneus longus, peroneus brevis, soleus, vastus medialis, gluteus medius, tibialis anterior

Timepoint

1- Before intervention 2- Immediately after the 1st session of intervention 3- After the last session of

intervention 4- Three months after the end of the last session of intervention

Method of measurement

Surface electromyography device (average amplitude of muscular activity 200 milliseconds before - 200 milliseconds after initial foot-ground contact)

Secondary outcomes

1

Description

Functional status scores

Timepoint

1- Before intervention, 2- After the last intervention session, 3- Three months after the last intervention session

Method of measurement

1- Foot and Ankle Ability Measure (FAAM), 2- Cumberland's Ankle instability index

2

Description

Dynamic postural stability

Timepoint

1- Before intervention, 2- After the last intervention session, 3- Three months after the last intervention session

Method of measurement

Scores of the Star Excursion Balance Test (SEBT)

3

Description

Time of figure of 8 hop test

Timepoint

1- Before intervention, 2- After the last intervention session, 3- Three months after the last intervention session

Method of measurement

Measurement of time for completing figure of 8 hop test

4

Description

Distance in triple hop test

Timepoint

1- Before intervention, 2- After the last intervention session, 3- Three months after the last intervention session

Method of measurement

Measuring distance in triple hop test

5

Description

Static postural control

Timepoint

1- Before intervention, 2- After the last intervention session, 3- Three months after the last intervention session

Method of measurement

Measuring stability indices in Biodex balance test

Intervention groups

1

Description

Intervention group: (1st intervention) subjects will complete progressive neuromuscular exercise, 2 sessions per week for 6 sequential weeks. Each session will last about 30 minutes. The subjects will also receive dry needling of peroneus longus and peroneus brevis trigger points, 1 session per week for 6 weeks.

Category

Rehabilitation

2

Description

Intervention group: (2nd intervention) subjects will complete progressive neuromuscular exercise, 2 sessions per week for 6 sequential weeks. Each session will last about 30 minutes. The subjects will also receive placebo dry needling of peroneus longus and peroneus brevis trigger points, 1 session per week for 6 weeks, while all stages of intervention is similar to real dry needling sessions.

Category

Rehabilitation

3

Description

Control group: Subjects will complete progressive neuromuscular exercise, 2 sessions per week for 6 sequential weeks. Each session will last about 30 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy clinic of faculty of rehabilitation of Shahid Beheshti university of medical sicences

Full name of responsible person

Mohsen Rustaei

Street address

Rehabilitation faculty of Shahid Beheshti university of Medical Sciences, opposit to Bu'ali hospital, Damavand St

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shahid Beheshti 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
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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