Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Core Muscle Strengthening Exercise on Pain, Static and Dynamic Balance in Amateur Athletes with Sub-Acute Lateral Ankle Sprain

Protocol summary

Study aim
The main purpose of this study is to use exercises to strengthen the central muscles of the trunk with the aim of increasing the stability of the ankle and improving the treatment results and helping athletes return to normal and sports activities.

Design
Randomized, single-blind, parallel-group controlled clinical trial. Randomization.com was used for randomization

Settings and conduct
The place of treatment is in Arjang Physiotherapy Clinic. 12 treatment sessions are performed for each person. Patients are blinded in the case of group therapy, who are randomized through the Randomization.com site and do not know about the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion: Amateur athletes between 18- 35 years old Amateur athletes who exercise 2 to 4 hours a week Grade 1 and 2 lateral ankle sprain that has been determined by an orthopedic specialist. The injury happened between 5 and 14 days ago Exclusion Criteria: Grade 3 ankle sprain Associated fracture of the lower extremities Chronic ankle injuries and open ankle wounds Painful medical syndrome, such as fibromyalgia, rheumatoid arthritis Use of pain medication within 7 days prior to the study Previous physical therapy intervention Syndesmosis injuries or medial ligament injuries Participants who had sensory defects (such as diabetes, previous nerve Injuries) Serious disease (e.g. disease of CNS, hemophilia, cancer, kidney disease, liver disease) Disability at doing side plunk for difference reasons

Intervention groups
Two groups including regular physiotherapy group and physiotherapy plus exercise to strengthen the core muscles of the body

Main outcome variables
Pain Static Balance Dynamic Balance Ankle Function Core Muscle Endurance

General information

Reason for update
The reason for the update is to change the type of study from single blinded to triple blinded

Acronym

IRCT registration information
IRCT registration number: **IRCT20240309061219N1**
Registration date: **2024-06-05, 1403/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-24, 1403/09/04**
Update count: **1**

Registration date
2024-06-05, 1403/03/16

Registrant information

Name
Alireza Hosseinzadeh Chaijan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 4268 5050

Email address
alirezahzch77@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-06, 1403/01/18

Expected recruitment end date
2024-07-10, 1403/04/20

Actual recruitment start date
2024-04-06, 1403/01/18

Actual recruitment end date
2024-09-05, 1403/06/15

Trial completion date
2024-09-05, 1403/06/15

Scientific title
Effect of Core Muscle Strengthening Exercise on Pain, Static and Dynamic Balance in Amateur Athletes with Sub-Acute Lateral Ankle Sprain

Public title
Effect of Core Exercises on Treatment of Ankle Sprain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Amateur athletes between 18- 35 years old Amateur athletes who exercise 2 to 4 hours a week Grade 1 and 2 lateral ankle sprain that has been determined by an orthopedic specialist. The injury happened between 5 and 14 days ago

Exclusion criteria:
Grade 3 ankle sprain Associated fracture of the lower extremities Chronic ankle injuries and open ankle wounds Painful medical syndrome, such as fibromyalgia, rheumatoid arthritis Use of pain medication within 7 days prior to the study Previous physical therapy intervention Syndesmosis injuries or medial ligament injuries Participants who had sensory defects (such as diabetes, previous nerve Injuries) Serious disease (e.g. disease of CNS, hemophilia, cancer, kidney disease, liver disease) Disability at doing side plunk for difference reasons

Age
From **18 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Actual sample size reached: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Block Randomization method is used for individual randomization through the Randomization.com site to randomize interventions on people.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients are blinded in this study. In fact, they do not understand the type of treatment that is going to be done on them. Also, the assessor and data analyst in this study do not know the type of treatment applied to the patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Tehran, intersection of Keshavarz Blvd and Qods Street, Central Headquarters Building of Tehran University of Medical Sciences, fifth floor, room 501

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2024-03-06, 1402/12/16

Ethics committee reference number
IR.TUMS.FNM.REC.1402.234

Health conditions studied

1

Description of health condition studied
Our study investigates the effect of strengthening the central muscles of the body on subacute external sprain of the ankle in amateur athletes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Dynamic balance in Y balance test

Timepoint
Before intervention, 2 ,4 weeks after intervention

Method of measurement
Y balance test

Secondary outcomes

1

Description
Static balance in balance error scoring system

Timepoint
Before intervention, 2 ,4 weeks after intervention

Method of measurement
Balance test error system scoring system

2

Description
Pain
Timepoint
Before intervention, 2 ,4 weeks after intervention
Method of measurement
Short form of Mcgill Pain Questionnaire

3

Description
Core muscle endurance
Timepoint
Before intervention, 2 ,4 weeks after intervention
Method of measurement
Mcgill isometric endurance test

4

Description
Ankle function
Timepoint
Before intervention, 2 ,4 weeks after intervention
Method of measurement
Foot and Ankle Ability Measure

5

Description
Quality of life
Timepoint
Before and 4 weeks after intervention
Method of measurement
World Health Organization Quality of Life Brief Version

6

Description
General self-efficacy
Timepoint
Before and 4 weeks after intervention
Method of measurement
Schwartz's general self-efficacy questionnaire

7

Description
Self-esteem
Timepoint
Before and 4 weeks after intervention
Method of measurement
Rosenberg self-esteem scale

8

Description
Life expectancy
Timepoint
Before and 4 weeks after intervention
Method of measurement
Snyder Adult Hope Questionnaire

Intervention groups

1

Description
Intervention group:This group will receive routine physiotherapy treatment plus core muscles strengthening exercises. Routine physiotherapy consists of pulsed ultrasound in the first two weeks for 10 minutes of pulse ultrasound with an intensity of 0.3 W/cm2, 30% duty cycle and 3 MHz frequency is used on the painful area of the lateral ankle malleolus. In the second two weeks, ultrasound is used for 6 minutes and intensity of 0.5 W/cm2, duty cycle of 50% and frequency of 3 MHz. Also, high frequency TENS (frequency 120 Hz and pulse duration 50 microseconds for 30 minutes) and range of motion exercises(these exercises include plantar flexion, dorsiflexion, inversion and eversion of the ankle in a painless range and 3 sets and 20 repetitions in each set, which are performed every day) will also be used. In addition to these exercises,will recieve strengthening exercises of the core muscles.In order to strengthen the core muscles of the trunk, we ask the person to lie on the opposite side of the injured side on the bed, and let the trunk and upper limbs hang over the edge of the bed, so that the strengthened (injured) side is up. Then the person tries to move his shoulder towards the pelvis by contracting the lateral muscles of the trunk. The therapist must fix his pelvis and lower limb (slightly above the ankle). To start the exercise, the patient's upper hand is on the hip and the lower hand is on the upper shoulder, and if the muscle strength increases,it can make the exercise more difficult by placing the patient's upper and lower arms behind his back. Finally, to progress the exercise again, the patient can perform the movement while lying on the Swiss ball. The person maintains the contraction for 15 to 30 seconds (depending on the person's strength) and does it 3 to 5 times a day. The next exercise is the side plank. At first, the person lies on the injured side on elbow and places the upper hand on the hip.While both knees are bent, he lifts the pelvis and trunk. To make the exercise more difficult at the same time as the muscle strength increases, he/she straightens the two knees and then lifts the trunk and pelvis. The person maintains both of these exercises between 10 and 60 seconds and performs between 3 and 5 times. The treatment of this group is done three sessions a week for 12 sessions.
Category
Rehabilitation

2

Description
Control group:This group will receive routine physiotherapy treatment.Routine physiotherapy consists of pulsed ultrasound in the first two weeks for 10 minutes of pulse ultrasound with an intensity of 0.3 W/cm2, 30% duty cycle and 3 MHz frequency is used on the painful area of the lateral ankle malleolus. In the second two weeks, ultrasound is used for 6 minutes and intensity of 0.5 W/cm2, duty cycle of 50% and frequency

of 3 MHz. Also, high frequency TENS (frequency 120 Hz and pulse duration 50 microseconds for 30 minutes) and range of motion exercises(these exercises include plantar flexion, dorsiflexion, inversion and eversion of the ankle in a painless range and 3 sets and 20 repetitions in each set, which are performed every day) will also be used.The treatment of this group is done three sessions a week for 12 sessions.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Faculty of Rehabilitation, Tehran University of Medical Sciences

Full name of responsible person
Alireza Hosseinzadeh

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Tehran, District 12, Enghelab St، Pich-e-Shemiran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Alireza Hosseinzadeh Chaijan

Position
Master of Science Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Position
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Latest degree
Bachelor

Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available