

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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/cm<sup>2</sup>, 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/cm<sup>2</sup>, 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 relieve 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/cm<sup>2</sup>, 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/cm<sup>2</sup>, 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

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1148965111

##### Phone

+98 21 7753 3939

##### Email

Alirezahzch77@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Ali Akbari Sari

##### Street address

Keshavarz Blvd., Qods st., Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

##### Phone

+98 21 8163 3698

##### Email

vcr@sina.tums.ac.ir

##### 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

##### Street address

No.1, Somayeh street, Emam Blvd, Kelachay town

##### City

Rudsar

##### Province

Guilan

##### Postal code

4491935651

##### Phone

+98 13 4268 5050

##### Fax

##### Email

Alirezahzch77@gmail.com

## Person responsible for scientific 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

##### Street address

No.1, Somayeh street, Emam Blvd, Kelachay town

##### City

Rudsar

##### Province

Guilan

##### Postal code

4491935651

##### Phone

+98 13 4268 5050

**Fax**

**Email**

Alirezahzch77@gmail.com

## Person responsible for updating data

### 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

**Street address**

No.1, Somayeh street, Emam Blvd, Kelachay town

**City**

Rudsar

**Province**

Guilan

**Postal code**

4491935651

**Phone**

+98 13 4268 5050

**Fax**

**Email**

Alirezahzch77@gmail.com

## 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