

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Study the effect of dry needling of leg muscles on ankle joint position sense and functional disability in patients with chronic ankle instability: a randomized clinical trial study

#### Protocol summary

##### Study aim

Study the effect of leg muscles dry needling on ankle proprioception and functional disability in patients with chronic ankle instability

##### Design

36 patients with chronic ankle instability are randomly divided into 2 groups. The study is a double-blind randomized clinical trial. Stratified Permuted Block Randomization method is used for randomization. In the intervention group, proneal muscles dry needling will be performed and in the control group, sham dry needling will be performed. Assessment of proprioception and functional disability will be done once before the intervention and once after the intervention.

##### Settings and conduct

This study is performed at the neuromuscular Rehabilitation Research Center. Patients are invited to participate in the study based on their physician's diagnosis

##### Participants/Inclusion and exclusion criteria

Entry requirements: Age between 18 and 50 years  
Having a history of ankle sprains at least once  
Have a history of at least one period of ankle emptying in the last 6 months  
Minimum pain intensity 3 on the pinnacle scale  
numerical pain scale  
Non-entry conditions: History of lower limb fractures  
History of lower extremity surgery  
Existence of any pathology in the lower extremities such as vascular diseases and osteoarthritis  
Pregnancy  
Medication  
Fear of needles  
Receive physiotherapy treatment for the lower extremities during the last 6 months

##### Intervention groups

In the intervention group, dry needling for leg muscles will be performed. In the control group, sham dry needling will be performed

##### Main outcome variables

Assessment of proprioception and functional disability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220130053889N1**

Registration date: **2022-02-21, 1400/12/02**

Registration timing: **prospective**

Last update: **2022-02-21, 1400/12/02**

Update count: **0**

##### Registration date

2022-02-21, 1400/12/02

##### Registrant information

##### Name

Atefeh Aminianfar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3344 1022

##### Email address

amiinhdn@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-04, 1401/01/15

##### Expected recruitment end date

2022-07-22, 1401/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Study the effect of dry needling of leg muscles on ankle joint position sense and functional disability in patients with chronic ankle instability: a randomized clinical trial study

**Public title**

The effect of dry needling on chronic ankle sprains

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Aged 18 to 50 years History of at least one ankle sprain At least one episode of giving away in the previous 6 months Ankle pain of intensity > 3 points on an 11- point numerical pain rate scale

**Exclusion criteria:**

Fracture in the lower extremity History of surgery in the lower extremity Any concomitant lower extremity pathology, for example, vascular disease and osteoarthritis Pregnancy Needle phobia Regular use of medication Previous physical therapy interventions received on the lower extremity within the previous 6 months

**Age**

From **18 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The samples are assigned (to two groups) randomly and using the method of random permutation blocks with 6 blocks of 6, assigned to the two groups. In this method, A will represent the intervention group and B will represent the control group. In this way, the order of A and B interventions in the form of blocks from 1 to 6 is determined by the methodological consultant of the project, and is provided to the executive supervisor of the project, and the researcher obtains an assignment from the executive supervisor to assign each qualified person. The supervisor first selects the block using a random number generator (or dice roll) and then the eligible individuals are assigned to one of the two groups A or B in the order specified in the table below (top to bottom). And the sequence of each item will be crossed out. It should be noted that if a block is selected based on random numbers that have already filled all 6 sequences, another random number will be selected again for that person.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The researcher will be blind to the intervention by employing the research assistant and not being in the intervention room. The outcome assessor will be different from the researcher and will only receive the study data with a code from the researcher and is not aware of the intervenors. In each group, they are not aware of the intervention of the other group

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committees of Semnan University Of Medical Sciences and Health Services

**Street address**

Semnan university of medical sciences , Basij Blvd , Semnan city

**City**

Semnan

**Province**

Semnan

**Postal code**

35147-99442

**Approval date**

2022-01-30, 1400/11/10

**Ethics committee reference number**

IR.SEMUMS.REC.1400.294

**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**

proprioception

**Timepoint**

Before the intervention and after the intervention

**Method of measurement**

Biodex Isokinetic Dynamometer

## 2

### **Description**

functional disability

### **Timepoint**

Before the intervention and after the intervention

### **Method of measurement**

Figure-8 hop test and Side-to-side hop test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Proneal muscles dry needling will be performed 2 sessions per week for 3 consecutive weeks. For dry needling the proneus muscles trigger points, the patient lies on the healthy side and the pelvis and knees are bent 90 degrees. The therapist stands in front of the patient and finds the trigger points in the muscle on the outside of the leg, cleans the skin with alcohol, and inserts the needle into the muscle from the inside out. The therapist dips the needle 10-15 mm to see the first twitch, then moves the needle 2-3 mm up and down for 30-45 seconds without turning.

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: To treat patients in this group, we will act in the same way as the treatment group, with the difference that we insert the needle superficially and away from the trigger points in the skin so that the patient can feel only the tip of the needle.

#### **Category**

Treatment - Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Neuromuscular Rehabilitation Research Center of  
Semnan University of Medical Sciences

##### **Full name of responsible person**

Atefeh Aminianfar

##### **Street address**

Qods Blvd, Semnan City

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Semnan

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35196-98375

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nmrrc@semums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Semnan University of Medical Sciences

##### **Full name of responsible person**

Majid Mirmohamad Khani

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Semnan University of Medical Sciences, Basij Blvd,  
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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**

Semnan 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**

Semnan University of Medical Sciences

##### **Full name of responsible person**

Atefeh Aminianfar

##### **Position**

Assistant Professor

##### **Latest degree**

Ph.D.

##### **Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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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