Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Iran (Islamic Republic of)

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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 interventors. 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
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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
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Position
Assistant Professor
Latest degree
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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