

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The immediate Effect of Ankle Muscles Dry Needling on Brain 's Functions in healthy and ankle functional instability during functional task by Functional Magnetic Resonance Imaging.

Protocol summary

Study aim

Comparison and determination of the effect of dry needling on the human brain by functional magnetic resonance imaging in healthy individuals and patients with ankle instability.

Design

A randomized double blinded clinical trial with the parallel group design of 21 subjects.

Settings and conduct

Patients are selected from the volunteers referring to the rehabilitation clinics of Tehran University of Medical Sciences and healthy subjects are selected from the students of Tehran University of Medical Sciences by registering personal information and evaluating the outcome variables. Participants are not aware of the difference in treatment techniques and the examiner is not aware of the allocation groups of participants. The performer of the intervention has no information about the results of the evaluations.

Participants/Inclusion and exclusion criteria

Healthy and right ankle sprain participants (age: 18-40). No history of sports activities (Baecke questionnaire). Ankle sprain's subjects should have at least grade two of sprain based on the West Point classification; exclusion criteria: Any history of neurological and cardiovascular diseases. Musculoskeletal disorder in other lower limb joints in ankle sprain subjects and any musculoskeletal disorder in lower limbs of the healthy participants. Any Contraindications of MRI.

Intervention groups

In two groups the needles are used in fast in fast out cone shape technique for ankle muscles, including the tibialis anterior and the peroneus longus(This method will be applied both in healthy and ankle impairment subjects). Each needle is applied for one minute. The number of treatment session will be one session. In another group, sham needles are inserted to the target

muscles and the same procedure will be applied.

Main outcome variables

Location of the activated brain area, dorsiflexor strength, dorsiflexor active range of motion, pain

General information

Reason for update

data acquisition time has been modified because of the technical adjustment of the fMRI in the Lab. Other modification: reliable questionnaire of Cumberland Ankle Instability Tool will be also used as one of the inclusion criteria for participants with ankle instability.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210713051875N2**

Registration date: **2022-12-11, 1401/09/20**

Registration timing: **prospective**

Last update: **2023-10-20, 1402/07/28**

Update count: **2**

Registration date

2022-12-11, 1401/09/20

Registrant information

Name

Roshanak Honarpisheh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-11, 1402/08/20

Expected recruitment end date

2024-04-17, 1403/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The immediate Effect of Ankle Muscles Dry Needling on Brain 's Functions in healthy and ankle functional instability during functional task by Functional Magnetic Resonance Imaging.

Public title

The Effect of Dry Needling on Human's Brain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy and right ankle sprain participants (18-40 years old) Subjects do not participate in any sports or physical activities, based on Baecke questionnaire (8 score or less) Contraindications of dry needling Subjects with right ankle sprain should have following conditions:1- at least 2 history of ankle sprains that has disturbed the daily activities of the person for at least one day and the symptoms of inflammation, swelling, pain and redness have been seen 2-Ankle instability will be diagnosed by a self-administered questionnaire of Cumberland Ankle Instability Tool 3- feeling of instability or sudden giving way of the ankle ,at least twice during the last 6 months Right domain leg

Exclusion criteria:

Any history of neurological and cardiovascular diseases musculoskeletal disorder in other lower limb joints in ankle sprain subjects and any musculoskeletal disorder in lower limbs of the healthy participants Any ankles' deformity Any medical conditions including headache , ... during study Drug abuse or any medical use Contraindications of MRI including any metal object in the body, pace maker and ... Drink caffeine couple of hours before brain scan

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **21**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the number of healthy subjects in each group,

the particular sort of intervention (real or sham needle) is written on a piece of paper. Each paper is placed in a sealed envelope. One envelope will be chosen randomly by the therapist at the beginning of the study session and the patient's intervention will be selected based on that. If any of the subjects is omitted from the study, one envelope related to the excluded subject's group will be replaced and they will be mixed again. Subjects with ankle impairment will receive real needling.

Blinding (investigator's opinion)

Double blinded

Blinding description

At first, necessary explanation about the study and its aims will given to the participants. The explanation of the existence of two groups are given to the healthy subjects; Whereas no information about the difference interventions between two groups will be given to them. There will be no connection between subjects of each groups. This way they will be blind regarding intervention methods. In addition examination will be preformed by a physiotherapist who is not aware of the participant's group. So examiner is blind to the treatment method of each participant.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee OF Nursing and Midwifery & Rehabilitation schools- Tehran university of Medical Sci

Street address

Quds Ave, Keshavarz Blvd.

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Tehran

Province

Tehran

Postal code

2181455618

Approval date

2022-11-28, 1401/09/07

Ethics committee reference number

IR.TUMS.FNM.REC.1401.115

Health conditions studied**1****Description of health condition studied**

Ankle functional instability

ICD-10 code

M25.371
ICD-10 code description
Other instability, right ankle

Primary outcomes

1

Description

Coordinates of maximum intensity; Voxel count; Peak intensity

Timepoint

During dorsiflexion movement (before dry needling intervention), during dry needling intervention, during dorsiflexion movement (after dry needling intervention)

Method of measurement

Functional magnetic resonance imaging machine

Secondary outcomes

1

Description

Dorsi flexor strength

Timepoint

Before intervention, immediately after intervention

Method of measurement

Manual dynamometer

2

Description

Active dorsi-flexor range of motion

Timepoint

Before intervention, immediately after intervention

Method of measurement

Standard goniometer

3

Description

Pain

Timepoint

Before intervention, immediately after intervention

Method of measurement

Persian version of McGill Pain Questionnaire Short-form

Intervention groups

1

Description

Intervention group: Dry needling is performed by fast in fast out technique for the tibialis anterior and peroneus longous muscles.

Category

Rehabilitation

2

Description

Control group: The sham dry needling procedure is

performed for one minute on the location of tibialis anterior and peroneus longous muscles.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of rehabilitation, Tehran University of Medical Science

Full name of responsible person

Roshanak Honarpisheh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotohi

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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
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

The raw data of research and its analysis will be available to the researcher if they request it.

When the data will become available and for how long

After the publication of articles resulting from the research.

To whom data/document is available

Researchers working in academic institution

Under which criteria data/document could be used

The data are only available to other researchers to study and evaluate treatment outcomes.

From where data/document is obtainable

Department of physiotherapy, School of Rehabilitation,

Enghelab St; Professor Soofia Naghdi Email address:
naghdi@sina.tums.ac.ir

What processes are involved for a request to access data/document

By sending an official E-mail to the corresponding author:

professor Soofia Naghdi (naghdi@sina.tums.ac.ir) and request the data. The researcher will be answered as soon as possible.

Comments