# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Study of the neurophysiologic effects of dry needling on quadriceps muscle fatigue of amateur healthy men athletes immediately and one hour after dry needling

## Protocol summary

**Study aim**
The study of the neurophysiologic effects of dry needling on quadriceps muscle fatigue of amateur healthy men athletes

**Design**
A parallel, randomized, double blinded, sham controlled clinical trial with 20 participants. Randomization is carried out with sealed envelops.

**Settings and conduct**
The study is done at the rehabilitation department of Tehran University. H-reflex of the quadriceps muscle (alpha-motorneuron excitability), single leg hop (function) and single leg stance (balance) are done by participants on their dominant lower extremity randomly. also the maximum isometric torque is measured by a handheld dynamometer and measuring the moment arm length. after that, squat protocol is used to induce quadriceps muscle fatigue. tests are repeated after fatigue. after that dry needle in the intervention group and sham needle in the placebo group are performed. tests are repeated after needling and also after a hour. to blinding, tests and measurements are done by the assessor, who is unaware of the groups of people, and intervention is done by another person.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria include the age of 18-40, doing minimum exercise of 3 one-hour sessions per week, no lower extremity injury and no previous experience of dry needle, and exclusion criteria include people's inability or dissatisfaction to continue the study, contraindications for dry needle and doing strenuous activity during 48 hours before the study.

**Intervention groups**
While the subject was in supine with the leg in an extended neutral position, points on the VM, VL, and the RF muscles were randomly needled. People in the placebo group get into the same position, and they are needled at the same points as the intervention group. In this group needles are plastic ones in the tubes.

**Main outcome variables**
maximum isometric torque of quadriceps, balance, function, Hmax/Mmax ratio

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20221201056676N1**
Registration date: **2023-05-16, 1402/02/26**
Registration timing: **prospective**

Last update: **2023-05-16, 1402/02/26**
Update count: **0**

**Registration date**
2023-05-16, 1402/02/26

**Registrant information**

**Name**
Melika Rostamkhani

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 6619 6145

**Email address**
melikarostamkhani137@yahoo.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-05-23, 1402/03/02

**Expected recruitment end date**
2023-07-23, 1402/05/01

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Study of the neurophysiologic effects of dry needling on quadriceps muscle fatigue of amateur healthy men athletes immediately and one hour after dry needling

**Public title**
Study of the effects of dry needling on fatigue
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
no history of lower extremity injury no vestibular disorders no cardio-vascular-pulmunary diseases no neuromusculoskeletal diseases age of 18-40 years minimum exercise of 1-hour, 3 sessions per week (at least 2 months) no pain in lower extremity in at least recent 2 months no Trypanophobia (needle phobia) no needle contradictions no history of dry needle experience
**Exclusion criteria:**
lack of consent have pain during the study inability to continue the test have strenuous physical activity 48 hours before the test being a physical therapy student
**Age**
From **18 years** old to **40 years** old
**Gender**
Male

**Phase**
N/A
**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
simple randomization with sealed envelops: every participants are given a personal information form. there are written A and B on these forms to determine the intervention and placebo groups. these forms are given to participants randomly. if someone get the A form, he would be in the intervention group and if he get the B form, he would be in the placebo group.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
to blinding, tests and measurements are done by the assessor, who is unaware of the groups of people. on the other hand intervention is done by another person. Also, for intervention, people in the placebo group are set on the same position as the intervention group and they get the sham needles (plastic needles on the tube) on the same points as the intervention group. these needles are put on the skin and are pushed on it, but they do not enter into body.
**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 department and Rehabilitation department of Tehran Univers
**Street address**
No. 20, West First Golzar Ave., Majdi Blvd., Artesh Highway
**City**
Tehran
**Province**
Tehran
**Postal code**
1956973773
**Approval date**
2022-11-28, 1401/09/07
**Ethics committee reference number**
IR.TUMS.FNM.REC.1401.111

## Health conditions studied

### 1

**Description of health condition studied**
fatigue
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
maximum isometric torque of quadriceps
**Timepoint**
measuring maximum isometric torque of quadriceps at the beginning of the study, after fatigue protocol, after intervention, and one hour after intervention
**Method of measurement**
handheld dynamometer

### 2

**Description**
function
**Timepoint**

measuring function at the beginning of the study, after fatigue protocol, after intervention, and one hour after intervention

**Method of measurement**

single leg hop test

**3**

**Description**

H/M ratio

**Timepoint**

measuring H/M ratio at the beginning of the study, after fatigue protocol, after intervention, and one hour after intervention

**Method of measurement**

electromyography (EMG)

## Secondary outcomes

**1**

**Description**

balance

**Timepoint**

measuring balance at the beginning of the study, after fatigue protocol, after intervention, and one hour after intervention

**Method of measurement**

single leg stance test

## Intervention groups

**1**

**Description**

Intervention group: An expert physical therapist qualified in DN performs the needling procedure of the Quadriceps Femoris of the dominant lower extremity. While the subject is in supine with the leg in an extended neutral position, points on the Vastus Medialis (VM), Vastus Lateralis (VL), and the Rectus Femoris (RF) muscles are randomly needled using stainless steel needles with a diameter of 0.3 mm and a length of 50 mm each for one minute using a fast in-fast out technique. The VM point is located at about 25% of the distance of a line from the medial superior border of the patella to the Anterior Superior Iliac Spine (ASIS); the VL point is located at the mid-thigh along a line from the lateral superior border of the patella to the apex of greater trochanter; the RF point is located at the mid-thigh along a line from the superior border of patella to the ASIS

**Category**

Rehabilitation

**2**

**Description**

Control group: Cases in this group are positioned as same as the intervention group. Sham needles, plastic needles in tubes, are applied to the same points. These needles are put on the skin and are pushed, but they do not insert into it.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Department of Rehabilitation of Tehran University of Medical Sciences

**Full name of responsible person**

Melika Rostamkhani

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Pich-e-Shemiran, Enghelab street

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rehabilitation@tums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotoohi

**Street address**

No. 5, Hoseini Alley, 21Metrijey Street, Ostadmoein Square

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**Province**

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**Postal code**

1341767177

**Phone**

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melikarostamkhani137@yahoo.com

**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**

Melika Rostamkhani

**Position**

master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**

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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 institutions.

**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 street; 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 Email to the corresponding author: professor Soofia Naghdi (naghdi@sina.tums.ac.ir) and requesting the data, the researcher will be answered as soon as possible.

**Comments**