# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 2026

## Comparison of the Immediate and Delayed Effects of Two Methods of Fast in fast out and Winding Dry needling in Gastrocnemius Muscle Trigger Points on Lower Extremity Function and Pain in Non-professional Athletes

## Protocol summary


**Study aim**

Comparison of the immediate and delayed effects of two methods of fast in fast out and winding dry needling in Gastrocnemius muscle trigger points on lower extremity function and pain in non-professional athletes

**Design**

One blind clinical trial will performed on two groups including control group with needles in a piston method, and the second group in a needle rotation method, which was randomized with software. Sample size will be 60 subjects.

**Settings and conduct**

Participants will be male athletes at the level of the sports clubs and sports teams of Semnan, who will have Gastrocnemius muscles trigger points . participants are divided into two groups which are blinded to other group. The groups will treated with two needle techniques. The jumping height will measured by the camera of motion analysis at the intervals before and after the treatment, at intervals of 24, 48, 72 hours and four weeks after treatment. The intensity of the pain will also measured based on the visual analog scale of pain before, during treatment, after treatment, and 24, 48, 72 hours, four weeks after treatment.

**Participants/Inclusion and exclusion criteria**

subjects will selected by examination. The presence of fibrous bundles in the muscle, sensitivity to touch, the presence of palpable or visible muscle fasciculation in the palpation and pain in posterior region of the leg while walking or running without morning symptoms that can be radicular or constant. Participants should have moderate pain intensity and based on the visual scale, the pain should be between 3 and 6. They should be athletes and running, jumping, abrupt change, fast running should be main component of their sports.they should have training at least two days a week.

**Intervention groups**

Individuals will divided into two groups. fast in fast out group and winding needling group

**Main outcome variables**

Pain and jumping height will be evaluated.


## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20160424027562N9**
Registration date: **2019-05-25, 1398/03/04**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-25, 1398/03/04**
Update count: **0**

**Registration date**

2019-05-25, 1398/03/04

**Registrant information**


**Name**

Roghayeh Mohammadi

**Name of organization / entity**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-05-22, 1398/03/01

**Expected recruitment end date**

2019-09-21, 1398/06/30

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

**Scientific title**
Comparison of the Immediate and Delayed Effects of Two Methods of Fast in fast out and Winding Dry needling in Gastrocnemius Muscle Trigger Points on Lower Extremity Function and Pain in Non-professional Athletes

**Public title**
The effect of dry needling on jumping and pain
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
The presence of fibrous bundle Touch sensitivity The presence of local or visible muscle fasciculation in palpation The presence of pain in the posterior region of leg muscles during walking or running without morning symptoms that can be radicular or constant Individuals should be athlete and running, jumping, sudden redirect and fast running should be the main components of their sports. They should practice at least two days a week Squatting should be part of their training program The participants should have moderate pain intensity and a VAS of between 3 and 6
**Exclusion criteria:**
Hypothyroidism Connective tissue tumor Anticoagulant drugs Blood disorders Local or diffuse infection Skin lesions, swelling, immune system disorders, vascular dysfunction and fear of dry needling History of any damage and treatment of vertebral column and lower extremity in the past three months The presence of 11 to 13 sensitive points that are indicative of fibromyalgia The presence of painful and sensitive points in other regions of lower extremity and trunk
**Age**
From **16 years** old to **40 years** old
**Gender**
Male

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

- Participant

**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
To ensure that two groups are matched in terms of sex as well as to achieve a complete randomized and balanced assignment, we will use stratified randomization method (layered) by stratified permuted block randomization. So individuals are divided into two stratum of male and female and for each stratum, a separate random assignment is continued until the optimal sample size is reached. For a random assignment in each stratum based on the sequences of the two methods A and B, six blocks are defined as follows and numbered from 1 to 6 respectively: AABB- BBAA- ABAB- ABBA- BABA- BAAB Then, blocks of random numbers are randomly selected by numbers 1 to 6. (numbers 0 and 7 to 9 are not the criteria for the decision). Thus, the type of intervention for each five people is determined respectively. Random allocation software will be used to construct the encryption tag, and then we will use the enclosed packet to hide it randomly.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
In order to blind the participants, the details of technique will not be explained for them and only the explanation of trigger points treatment by needling will be clarified. Also the individuals of each group will not be informed of the existence of the other group, to achieve this purpose, two groups will be visited on different days to get treatment and record jumping.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Semnan University of Medical Sciences
**Street address**
Semnan University of Medical Sciences, Basij Blvd, Semnan
**City**
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**Province**
Semnan
**Postal code**
3514799442
**Approval date**
2019-03-16, 1397/12/25
**Ethics committee reference number**
IR.SEMUMS.REC.1397.307

## Health conditions studied

### 1

**Description of health condition studied**
Myofascial trigger point
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Vertical jumping
**Timepoint**
At the beginning of the study, 24, 48, and 72 hours, also four weeks after applying the needle dry technique
**Method of measurement**
Motion analysis system

## Secondary outcomes

### 1

**Description**
Pain
**Timepoint**
At the beginning of the study, 24, 48, 72, and four weeks after applying the needle dry technique
**Method of measurement**
Visual analogue scale

## Intervention groups

### 1

**Description**
Control group: This group receives the usual dry needling method. Dry needling is applied to the trigger points of the Gastrocnemius muscle by means of a piston method. In this group, initial evaluations and the jumping base are recorded. The next day, the patient finds a dry needling at a depth of 3 cm on trigger points. In this method, the needle is 0.25 mm in diameter and 5 cm in length, and the needle enters the trigger point after passing through the skin, then it is removed to close the skin and then into a slightly spaced fan shape applied on trigger points, This will continue until muscle twitching is seen. After the twitch muscle is visible, it remains in the trigger point for ten minutes.Then the needle is removed and three jumps are taken from the participant, jump height is recorded by the motion analyzer. This device is a Qualysis brand and is made in the sweden country. The vertical jump is recorded by two cameras and the recording frequency is 100 Hz . Average jumps will be compared with the second intervention group.
**Category**
Rehabilitation

### 2

**Description**
Intervention group: This group receives the dry needle rotation method. In this group, initially, initial evaluations and the jump base are recorded. The next day, the patient finds a dry needle at a depth of 3 cm on trigger points. In this method, the needle is 0.25 mm in diameter and 5 cm in length. The needle passes through the skin and enters the trigger points. After insertion of the needle with a frequency of two Hz for 30 seconds in the opposite direction We turn the clock and rest for thirty seconds. It will be repeated for ten minutes. Then the needle is removed and three jumps are taken from the participants, jump height is recorded by the motion analyzer. This device is a Qualysis brand and is made in the sweden country. The vertical jump is recorded by two cameras an The recording frequency is 100 Hz . Average jumps will be compared with the second intervention group.
**Category**
Rehabilitation

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Neuromuscular Rehabilitation Research Center
**Full name of responsible person**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
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**Full name of responsible person**
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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**
Roghayeh Mohammadi
**Position**
Assistant Professor
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## Person responsible for updating data

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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**
Yes - There is a plan to make this available
**Informed Consent Form**
Yes - There is a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
All data can be shared after being unidentified.
**When the data will become available and for how long**
The beginning of the access period is one month after the results are published.

**To whom data/document is available**

All those who need research results can receive the study documentation.

**Under which criteria data/document could be used**

All people who use the information are required to mention the source

**From where data/document is obtainable**

To receive the information, they can contact the research author at the Faculty of Rehabilitation, Semnan University of Medical Sciences.

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

After receiving the email from the applicant, the applicant will be sent a document within two weeks

**Comments**