

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4180

Email address

mohammadpt@semums.ac.ir

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

Semnan

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

Roghayeh Mohammadi

Street address

Neuromuscular Rehabilitation Research Center,
Ghods Blvd, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3519698375

Phone

+98 23 3332 8502

Email

mohamadipt@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr Parviz Kokhaei

Street address

Semnan University of Medical Sciences, Basij
Boulevard, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

P_kokha@yahoo.com

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

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation Faculty, Semnan University of Medical Sciences, 5 kilometer of Damghan Road, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3365 4180

Fax**Email**

mohamadipt@gmail.com

Web page address**Province**

Semnan

Postal code

3514799442

Phone

+98 23 3365 4180

Fax**Email**

mohamadipt@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Roghayeh Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation Faculty, Semnan University of Medical Sciences, 5 kilometer of Damghan Road, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3365 4180

Fax**Email**

mohamadipt@gmail.com

Web page address**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.

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Roghayeh Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Rehabilitation Faculty, Semnan University of Medical Sciences, 5 kilometer of Damghan Road, Semnan

City

Semnan

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