Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effects of dry needling on sonoelastographic and biomechanical indices of hamstrings muscle flexibility in individuals with hamstring shortness

Protocol summary

Study aim
Assessing the effects of dry needling on sonoelastographic and biomechanical indices of hamstring muscle flexibility in individuals with hamstring shortening

Design
A clinical trial with a control group, parallel groups, double-blind, randomized design, phase 1, has been conducted on 26 patients. Randomization was done using randomization.com

Settings and conduct
This study aims to investigate the effects of dry needling on the stiffness and flexibility of hamstring muscle components at Shariati Hospital in Tehran. Participants will be randomly assigned to one of two groups: the dry needling group and the sham dry needling group. Both participants and assessors will be blind to the treatment group. The treatment to be given will be determined by the letters in a sealed envelope, which will be given to the therapist during the therapy session. The treatment will be administered in a single session, and the outcome measures will be evaluated before the intervention, 15 minutes after the intervention, and one month later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Women and men aged between 18 to 40 years old 2. Hamstring flexibility reduction of over 20 degrees based on the knee extension test 3. Individuals with level 3 activity according to the Tegner activity scale 4. Normal BMI between 20-25 kg/m² Exclusion criteria: 1. Lower back pain or hamstring injury within the past year 2. Orthopedic or neurological disorders in the lower extremities within the past year 3. Participation in stretching or sports activities 4. Previous dry needling treatment 5. Limited mobility in other lower extremity joints 6. Contraindications to dry needling 7. Unwillingness to participate in the study

Intervention groups
The dry needling group and the sham dry needling group

Main outcome variables
Shear elastic modulus, Muscle compliance, and Stiffness, Passive knee extension test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230611058456N1**
Registration date: **2023-07-10, 1402/04/19**
Registration timing: **prospective**

Last update: **2023-07-10, 1402/04/19**
Update count: **0**

Registration date
2023-07-10, 1402/04/19

Registrant information

Name
Razieh jahan fard

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
2023-08-23, 1402/06/01

Expected recruitment end date
2024-01-25, 1402/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effects of dry needling on sonoelastographic and biomechanical indices of hamstrings muscle flexibility in individuals with hamstring shortness

Public title

Investigating the effects of dry needling on sonoelastographic and biomechanical indices of hamstrings muscle flexibility in individuals with hamstring shortness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women between the ages of 18 and 40 More than 20 degrees reduction in hamstring flexibility based on PKET knee extension test

Exclusion criteria:

History of low back pain and lower limb neurological and orthopedic disorders in the past year Participation in sports and stretching activities Contraindications for dry needling

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **26**

Randomization (investigator's opinion)

Randomized

Randomization description

Using computer-generated random codes through the website randomization.com, individuals will be randomly assigned to two groups in equal numbers based on a block size of 4 by someone outside of the research team. The randomization will be concealed using a sealed envelope prior to the start of the study, and the evaluator and patients will be blinded to the process. Upon arrival, individuals will be assigned to either the dry needling or sham needling group based on the letters A and B in their packet.

Blinding (investigator's opinion)

Double blinded

Blinding description

Using computer-generated random codes through the website randomization.com, individuals will be randomly assigned to two groups in equal numbers based on a block size of 4 by someone outside of the research team. The randomization will be concealed using a sealed and waxed envelope prior to the start of the study, and the evaluator and patients will be completely blind to the process. Upon arrival, individuals will be assigned to either the dry needling or sham needling group based on the letters A and B in their packet. And the therapist, in the absence of evaluators, will provide the desired treatment based on the letter in the packet. To simulate the sensation of dry needling, a thin monofilament will be used and moved slowly on the skin for one minute at each point to mimic the actual sensation of the dry needle's contact and tapping.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran, Enghelab Street, Pich-e-Shemiran, at the corner of Safi Ali Shah Street, the Rehabilitation College

City

Tehran

Province

Tehran

Postal code

6511111489

Approval date

2023-05-29, 1402/03/08

Ethics committee reference number

IR.TUMS.FNM.REC.1402.039

Health conditions studied

1

Description of health condition studied

Individuals with hamstrings shortening

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The shear wave elasticity modulus is a continuous quantitative dependent variable that is one of the outputs of the elastography device, and shows tissue stiffness quantitatively in kilopascals.

Timepoint

The shear modulus of the muscular components of the hamstring is measured at the beginning of the study (before the start of the intervention) and 15 minutes and one month after the therapeutic session.

Method of measurement

To measure this variable, the participant will lie in a supine position. To prevent hip rotation, the anterior superior iliac spine regions of the participant's pelvis will be attached to the bed with a strap. Additionally, the opposite leg will be fixed to the treatment bed with another strap from the thigh area. The dominant leg under examination will be placed at a hip angle of 90 degrees and a knee angle of 45 degrees on a wooden platform. The shear elastic modulus for the semitendinosus, semimembranous, and biceps femoris muscle balance will be measured in the dominant leg. To accurately and stably measure the transducer, it must be placed longitudinally with the muscle fibers. The points under examination will be the midpoint of the femur from the greater trochanter to the medial epicondyle for the ST and SM muscles and to the lateral epicondyle for the BF muscle. These anatomical points will be confirmed by touch and B-mode images. The ultrasound transducer (50 mm in length, linear SL-15-4) will be placed on the areas under examination. Imaging will be recorded 5 seconds after placing the transducer on the target area to show a stable color distribution of the target area. The target area will be adjusted close to the center of the image of the muscle balance, and the mean wave velocity (m.s-1) will be automatically measured using a circular area with a diameter of 11 mm near the center of the target area. Based on this measurement, the shear elastic modulus will be calculated automatically in kilopascals. To prevent the stress-relaxation phenomenon and its effect on flexibility, each component of the muscle will be measured in less than 10 seconds, and the order of measuring different muscle components will be randomized.

2

Description

Compliance is an index related to the viscoelastic properties and contractile surface features extracted from the motor nerve's electrical activity. It is calculated by determining the ratio of changes in the angle of knee extension to changes in the inactive torque of the hamstring muscle during the passive knee extension test.

Timepoint

The compliance of the hamstring muscles is measured at the beginning of the study (before the start of the intervention) and 15 minutes and one month after the therapeutic session.

Method of measurement

The compliance of the muscle is indirectly measured by the compliance formula, which is equal to the ratio of changes in the passive knee extension angle to changes in non-active torque. To calculate this measure, the minimum angle and non-active torque of the hamstring muscle at these two angles during the passive knee extension should be recorded. The participant will be placed in the position mentioned in the passive knee extension test. While the evaluator places the dynamometer under the participant's heel, the passive knee will be opened until the participant feels a slight stretch. This point will be the starting point for compliance calculation. At this point, the force will be recorded by the dynamometer, and the angle will be measured . The tester then continues passive knee extension until the participant feels discomfort and intolerance to the stretch. This angle will be considered the second measurement point. he angle and magnitude of force at each point will be recorded again using a dynamometer. Measurements of angles and forces are performed three times at each inactive range of motion point, and the average of the three measurements is used for analysis and evaluation. The forces recorded by the dynamometer at the two angles are measured in Newtons and then the resulting number is multiplied by the length of the leg, which is the axis of motion torque, to convert it to torque.The length of the leg is equal to 0.285 times the height of the individual in meters, according to anthropometric coefficients provided in the sources.0.285 times the height of the individual in meters = length of the leg.At each point of the aforementioned points, to correct the effect of gravity and obtain the net muscle force, the weight of the leg is measured according to the following formulas, and the force obtained by the dynamometer will be reduced.Weight of leg x 9.81 x cos α = gravity correction0.06 x weight of individual in kilograms = weight of legTherefore, for each point of the inactive range of motion, the measurement steps are as follows: Use a dynamometer to measure the force at the desired point. Calculate the length of the leg based on the individual's height. Calculate the gravity correction based on the weight of the leg and the angle α measured by the angle gauge. Reduce the measured force obtained by the dynamometer with the gravity correction to obtain the net muscle force.Since angle and force measurements are performed three times at each point and the average of the three measurements is used for analysis and evaluation, the resulting measurement accuracy will be much higher.

3

Description

Muscle stiffness is a continuous quantitative dependent variable and refers to the ability of the tissue inside and around the muscles to increase their length. It is defined by calculating the ratio of changes in force or resistance to changes in length, and is essentially the inverse of compliance.

Timepoint

Muscle stiffness of the hamstrings is measured at the beginning of the study (before starting the intervention) and at 15 minutes and one month after the therapy session.

Method of measurement

In this study, since muscle stiffness is actually the inverse of inactive compliance, the inverse of the mentioned ratio for compliance as inactive stiffness is considered.

Secondary outcomes

1

Description

Passive Knee Extension Test (PKET): A continuous quantitative dependent variable that is determined by measuring the range of knee extension in the PKET test using an inclinometer and a degree scale. The maximum range of knee extension in the PKET test is determined by the onset of resistance of the knee flexor muscles against extension.

Timepoint

Measurement of this outcome will be performed at the beginning of the study (before starting the intervention) and will be repeated again at 15 minutes and one month after the intervention.

Method of measurement

To perform this test, the participant will lie supine on a treatment table. To prevent hip rotation, the ASIS regions of the participant's hips will be secured to the table using a strap. Additionally, the opposite leg will be secured to the treatment table from the thigh region using another strap. A wooden rectangular cube with a height of 37 cm, width of 83 cm, and depth of 31 cm will be used to position the hip of the participant in a 90-degree flexion position. To stabilize the hip position, the wooden cube will be secured to the treatment table using a strap to prevent any movement or changes in the hip angle. While the participant's ankle is in a neutral position, the evaluator will place the participant's knee in a 90-degree passive position. As a result, the participant's hip and knee will be positioned in a 90-90 degree position. From this position, the evaluator will passively open the knee until they feel firm muscular resistance for continued movement or until the patient reports strong but tolerable tension. The degree of knee extension will be measured using a goniometer or inclinometer. To measure the angle of passive knee extension, the bony landmarks of the lateral femoral epicondyle, lateral femoral condyle, and greater trochanter of the femur will be previously marked. The measurement of this outcome will be performed before starting the intervention, 15 minutes, and one month after the intervention. At each time point, the measurement will be repeated three times with one minute of rest between measurements, and the mean of the three measurements will be used for analysis.

2

Description

Passive peak torque: A continuous quantitative dependent variable that is defined as the maximum resistive force against passive muscle stretch and is determined by calculating and measuring in Newton meters.

Timepoint

Measurement of this outcome will be performed at the beginning of the study (before starting the intervention) and will be repeated again at 15 minutes and one month after the intervention.

Method of measurement

The participant will be positioned as before. Using a handheld dynamometer, the passive force at the point mentioned earlier to measure compliance, where the participant reports discomfort and intolerance to stretch, will be obtained. The maximum passive torque at this point in the range of motion will be calculated using the formula (passive torque = force * moment arm length). This test will be repeated three times with one minute of rest between measurements, and the mean of the three measurements will be used for analysis.

3

Description

Stretch tolerance: a continuous quantitative dependent variable defined as the ability to tolerate the discomfort during stretching, determined by the degree of knee extension in the passive knee extension test using a goniometer or inclinometer.

Timepoint

Measurement of this outcome will be performed at the beginning of the study (before starting the intervention) and will be repeated again at 15 minutes and one month after the intervention.

Method of measurement

In this measurement, we will also position the lower limb in the passive knee extension test using a wooden box and straps. The evaluator will passively move the knee from a 90-degree flexion position towards extension until the participant expresses discomfort and intolerance to stretch in the posterior thigh muscles. At this point, the evaluator will measure the degree of knee extension using a goniometer or inclinometer. This procedure will be repeated three times with one minute of rest between measurements, and the mean of the three measurements will be used for analysis.

4

Description

Active straight leg raise (ASLR): A continuous quantitative dependent variable that is determined by performing the active SLR test using a digital inclinometer and measuring the degree of hip flexion.

Timepoint

Measurement of this outcome will be performed at the beginning of the study (before starting the intervention) and will be repeated again at 15 minutes and one month after the intervention.

Method of measurement

To measure this outcome, the participant will lie in a supine position. The opposite lower limb will be secured to the fixed bed using a strap to prevent hip flexion and minimize compensatory movements. The participant will be instructed to actively lift the lower limb by hip flexion, keeping the knee in full extension and the ankle in dorsiflexion. Measurement will be performed using a digital inclinometer connected to a 15 cm bar placed under the tibial tuberosity in the longitudinal direction. This test will be repeated three times with one minute of rest between measurements, and the mean of the three measurements will be used for analysis.

Intervention groups

1

Description
Intervention group: Dry needling intervention: An experienced and trained physiotherapist will perform dry needling on the hamstrings of the participants. The patient is asked to lie prone on a treatment table with a pillow placed under their ankle. The skin over the posterior thigh is cleaned with alcohol. The dry needling intervention is performed using a sterile, disposable, and non-corrosive acupuncture needle with a length of 60 mm and a diameter of 0.30 mm with a quick in-and-out technique and a conical movement at three points on the hamstring muscles, including one point on the semimembranosus and semitendinosus muscles and two points on the long and short heads of the biceps femoris muscle, randomly and for one minute at each point. The depth of needle penetration for the dry needling intervention varies based on the participant's physical condition. The point related to the semimembranosus and semitendinosus muscles is located at 60% of the proximal head of the line that connects the ischial tuberosity to the medial epicondyle of the femur, and the point related to the long and short heads of the biceps femoris muscle is located approximately at 30% and 60% of the proximal head of the hypothetical anatomical line that connects the ischial tuberosity to the head of the fibula, respectively.

Category
Rehabilitation

2

Description
Control group: Dry needling intervention with sham: The target points for the dry needling intervention with sham will be the same as the dry needling group, except that a monofilament needle (manufactured by GIMA) will be used instead of a dry needle. Other steps will be the same as described above. The monofilament needle will be gently moved on the skin at each point for one minute to simulate the sensation of needle insertion without actually penetrating the skin.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital

Full name of responsible person
Razieh jahan fard

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No.1, Jalal Al-e Ahmad Highway, North Kargar Ave., Tehran, Iran

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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
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
Razieh Jahan fard

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
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Person responsible for scientific inquiries

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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
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
Raw data of the research and its analysis will be provided upon request by the researchers.
When the data will become available and for how long
After the publication of articles resulting from research.
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
The data is only available to other researchers for the study of treatment results.
From where data/document is obtainable
Department of Physiotherapy, Faculty of Rehabilitation, Enghelab St. Dr. Zinat Ashnagar, Iran. Email: z-ashnagar@sina.tums.ac.ir
What processes are involved for a request to access data/document
By sending an official academic email to the corresponding author: Dr. Zinat Ashnagar (z-ashnagar@sina.tums.ac.ir) and the request for documents will be answered as soon as possible.
Comments