

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Shear wave elastography assessment of hamstring muscle stiffness pre- and post Stretching and strengthening exercise training in patients with tight hamstring muscle

Protocol summary

Study aim

To assess hamstring muscle stiffness using shear wave elastography before and after stretching and strengthening exercise training in patients with tight hamstring muscles.

Design

Shear wave elastography will use to evaluate hamstring stiffness at baseline, 4 weeks and 12 weeks Range of motion will measure with a goniometer Muscle strength will assess with a handheld dynamometer Measurements will perform twice per muscle and averaged

Settings and conduct

Measurement locations will confirm using an ultrasound transducer to show the shear elastic modulus in the region of interest with stable color distribution.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Clinical examination by a physical medicine and rehabilitation specialist Goniometry to measure hip flexion and knee extension angles Age range: 20-40 years Exclusion Criteria: Any underlying joint disease in the hip and knee ROM disorders due to pain, such as radiculopathies and muscle problems Currently participating in sports competitions Cardiovascular disease or other serious systemic illness Lower limb stretching or strengthening exercises in the past 6 months Previous knee or hip surgery Old fractures or presence of cysts/blocks in the thigh or le

Intervention groups

Patients will undergo baseline ultrasound to measure muscle elasticity. They then will receive supervised hamstring stretching and strengthening exercises 3 times/week for 3 months under a rehabilitation specialist.

Main outcome variables

The main outcome will change in hamstring muscle stiffness measured by shear wave elastography. Secondary outcomes will include range of motion, muscle strength, and patient-reported functional

outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240425061570N1**

Registration date: **2024-06-01, 1403/03/12**

Registration timing: **registered_while_recruiting**

Last update: **2024-06-01, 1403/03/12**

Update count: **0**

Registration date

2024-06-01, 1403/03/12

Registrant information

Name

Leila Aghaghazvini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 1000

Email address

aghaghazvini.leila@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-18, 1403/02/29

Expected recruitment end date

2025-05-19, 1404/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Shear wave elastography assessment of hamstring muscle stiffness pre- and post Stretching and strengthening exercise training in patients with tight hamstring muscle

Public title

Shear wave elastography assessment of hamstring muscle stiffness pre- and post Stretching and strengthening exercise training in patients with tight hamstring muscle

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Clinical examination by a physical medicine and rehabilitation specialist (esteemed faculty of Tehran University of Medical Sciences) Goniometry and measurement of the angle between leg and femur in hip joint flexion and knee joint extension

Exclusion criteria:

Any underlying joint disease in the hip and knee joints ROM disorders due to pain in conditions such as radiculopathies and muscular problems Currently participating in sports competitions Cardiovascular disease or any other serious systemic disease.Strengthening exercises on the lower limbs in the past 6 months Previous knee or hip surgery Old fractures or the presence of a cyst or block in the thigh or shin

AgeFrom **20 years** old to **40 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

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

Ethics committee of Shariati hospital Tehran
University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Sixth
Floor, Central Organization of Tehran University of
Medical Sciences, Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419943471

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

IR.TUMS.SHARIATI.REC.1402.078

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

Patients with tight hamstring muscle problem

ICD-10 code

G71

ICD-10 code description

Primary disorders of muscles

Primary outcomes**1****Description**

Range of motion is measured using a goniometer, and muscle strength is evaluated using a hand-held dynamometer. Functional outcomes reported by participants will also be assessed using the Lower Extremity Functional Scale (LEFS).

Timepoint

Sonoelastography is used to evaluate hamstring muscle stiffness at the beginning, 4 weeks and 12 weeks.

Method of measurement

Findings The participant lies on his stomach and his knee is bent to 90 degrees and the ultrasound probe is placed longitudinally on the hamstring muscles. Shear elastic modulus of ST, SM and BF muscles in dominant leg using ultrasound shear waves with Aixplorer device; SuperSonic Imagine is measured. Measurement sites were defined as the midpoint of the femur from the greater trochanter to the medial epicondyle for the ST and SM muscles, and to the lateral epicondyle of the femur for the BF muscle. These anatomical points are confirmed by palpation and B-mode images. An ultrasound transducer was placed at the measurement sites, parallel to the direction of the muscle fibers as determined by tracking multiple fascicles without interruption across the B-mode image. For each muscle, images were taken after the transducer was held at the

measurement site for approximately 5 seconds until To confirm that the shear elastic modulus in the desired area of color distribution shows stability. Measurements will be performed twice for each muscle and the average values will be used for statistical analysis. The target region is set near the center of the muscle bulk image, and the average shear wave propagation speed (m/s) of a circle with a diameter of 11 mm, which is set near the center of the target region, will be automatically calculated.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Under the supervision of a respected specialist in physical medicine and rehabilitation, for three months, three times a week, patients undergo exercise treatments, including strengthening and stretching exercises for the hamstring muscles. The stretching part of the exercises focuses on static stretching (passive single leg raise, Hurdler stretch and knee to chest), while the strengthening part includes exercises such as wall squat, bridge and lunge.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Leila Aghaghazvini

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Akbari Sari

Street address

Vice Chancellor for Research and Technology, Sixth Floor, Central Organization of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd.

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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

Leila Aghaghazvini

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Radiology

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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

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

After printing the results as an article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For further research purposes and analysis

From where data/document is obtainable

In order to receive the data, it is necessary to refer to the scientific accountant or the corresponding author of the article

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

An official letter or e-mail

Comments