Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+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

Age
From **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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Shariati Hospital, Jalal-e-Al-e-Ahmad Hwy

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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

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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 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
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