Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

To compare the effects of low-load resistance training with and without blood flow restriction on thickness, strength and pain of shoulder girdle muscles in individuals with shoulder impingement syndrome

Protocol summary

Study aim
Investigating the effects of low-load resistance training combined with blood flow restriction on the thickness and strength of the supraspinatus, infraspinatus, middle trapezius, and biceps muscles and its pain-reducing effects in individuals with shoulder impingement syndrome

Design
a pragmatic, parallel-group, single-blind (with blinded outcome assessment), randomized controlled trial (RCT)

Settings and conduct
This single-blind trial at Amir Alam Hospital randomly allocates patients with shoulder impingement to receive 12 sessions of low-load resistance training, either with real BFR or with a sham BFR cuff. Participants and outcome assessors are blinded to the allocation, while the treating therapist is not. All patients also receive standard passive physiotherapy in each session consisting of TENS, US and hotpack.

Participants/Inclusion and exclusion criteria
Inclusion Criteria Age range of 40 to 60 years Literacy in Persian Shoulder pain with a maximum duration of 3 months since onset Nighttime shoulder pain or pain during overhead activities with a VAS score ≥ 3 Positive Painful arc test and at least three of the following tests: • Neer • Hawkins-Kennedy • Empty can • Infraspinatus Exclusion Criteria Contraindications to the use of BFR Simultaneous pain in both shoulders Diagnosis of frozen shoulder Positive drop arm test indicating a complete rotator cuff tear History of surgery, fracture, or dislocation in the shoulder region Use of anti-inflammatory drugs during the daytime while undergoing the physiotherapy course

Intervention groups
Group 1: Low-load resistance training (at 20-40% of 1RM) with BFR (LLRT+BFR group) Group 2: Low-load resistance training (at 20-40% of 1RM) without BFR (LLRT group)

Main outcome variables
muscles thickness muscles strength pain (NRPS) pain pressure threshold SPADI questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251202068202N1**
Registration date: **2025-12-10, 1404/09/19**
Registration timing: **prospective**

Last update: **2025-12-10, 1404/09/19**
Update count: **0**

Registration date
2025-12-10, 1404/09/19

Registrant information

Name
Bahram Tabatabaei

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
2025-12-22, 1404/10/01

Expected recruitment end date
2026-03-01, 1404/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
To compare the effects of low-load resistance training with and without blood flow restriction on thickness, strength and pain of shoulder girdle muscles in individuals with shoulder impingement syndrome

Public title
Comparing the effects of low-load resistance training with and without BFR in shoulder impingement syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 40 to 60 years Literacy in Persian experiencing shoulder pain for a maximum of 3 months Shoulder pain at night or during overhead activities greater than or equal to 3 based on VAS scale Positive Painful arc test and at least three of the following tests: Neer- Hawkins-kennedy- Empty can- infraspinatus
Exclusion criteria:
Contraindications for the use of BFR, including:• History of blood clots (DVT)• Blood pressure higher than 180 mmHg• Acute infection, peripheral vascular problems, varicose veins, or cancer.• History of hemorrhagic or thrombotic strokes.• History of arterial fibrillation Simultaneous pain in both shoulders Suffering from frozen shoulder Positive drop arm test indicating a complete rotator cuff tear History of surgery, fracture, or dislocation in the shoulder area Use of anti-inflammatory drugs during the day while undergoing the physiotherapy course
Age
From **40 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
The method used is balanced block randomization with a block size of 4. The unit of randomization is the individual participant. The study did not employ stratified randomization, meaning no specific stratification variables (such as age or disease severity) were used to create subgroups before randomization. The primary tool for implementing randomization was sequentially numbered, sealed, opaque envelopes. The random sequence was built by an independent researcher prior to the study's commencement. This was done by listing all possible combinations that would result in 2 allocations to Group A (LLRT) and 2 allocations to Group B (LLRT+BFR) within each block of 4 participants. This sequence was transcribed and placed into the sealed envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
This trial implements a structured blinding protocol where participants are blinded to their group assignment through allocation concealment using sequentially numbered, sealed, opaque envelopes, coupled with a sham procedure for the control group to mimic the sensory experience of the BFR cuff. The treating physiotherapist administering the interventions cannot be blinded due to the necessary application of the BFR technique. The principal investigator overseeing the trial remains blinded to group allocation during active data collection and analysis to prevent bias. Crucially, all outcome assessors are blinded: a clinical assessor, separate from the treating therapist, conducts all physical and questionnaire-based evaluations without knowledge of the assignment, and a radiologist performs all ultrasound measurements independently with no information on the participant's group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Amir A'lam Hospital Complex
Street address
Amiralam Hospital- Beginning of Saadi Street- Enghelab Street (Dorvaze Dolat)-Tehran
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Postal code
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Approval date
2025-05-20, 1404/02/30
Ethics committee reference number
IR.TUMS.AMIRALAM.REC.1404.008

Health conditions studied

1

Description of health condition studied
shoulder impingement syndrome

ICD-10 code
M75.4
ICD-10 code description
Impingement syndrome of shoulder

Primary outcomes

1

Description
isometric muscle strength of the rotator cuff muscles (supraspinatus)
Timepoint
pre and post intervention
Method of measurement
hand-held, fixed dynamometer

Secondary outcomes

1

Description
Thickness of supraspinatus, infraspinatus, middle trapezius, and biceps muscles at rest
Timepoint
pre and post intervention
Method of measurement
B-mode ultrasonography (model: Supersonic MACH30)

2

Description
night pain and pain while elevating the shoulder
Timepoint
pre and post intervention
Method of measurement
Numeric pain rating scale

3

Description
Pain pressure threshold on 2 points (end of supraspinatus muscle and thenar area of the affected side)
Timepoint
pre and post intervention
Method of measurement
digital algometer

4

Description
functional pain and disability
Timepoint
pre and post intervention
Method of measurement
Shoulder Pain and Disability Index questionnaire

Intervention groups

1

Description
Intervention group: Low-load resistance training (LLRT) with Blood Flow Restriction (BFR). Participants in this group will perform exercises at 20-40% of 1RM. An active BFR cuff will be applied to the proximal arm and inflated to a pressure set at 50% of the individual's pre-determined Limb Occlusion Pressure (LOP) to partially restrict arterial inflow and venous return during exercise. This group will also receive standard passive physiotherapy (hot pack, TENS, ultrasound).
Category
Treatment - Other

2

Description
Control group: Low-load resistance training (LLRT) with sham Blood Flow Restriction (BFR). Participants in this group will perform exercises at 20-40% of 1RM. A sham BFR cuff will be applied to the proximal arm; it will be inflated to a minimal, non-therapeutic pressure to provide the sensory experience without creating meaningful blood flow restriction. This group will also receive standard passive physiotherapy (hot pack, TENS, ultrasound).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir A'lam Hospital
Full name of responsible person
Dr. Mostafa Rahimi
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Sponsors / Funding sources

1

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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

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Position
MSc student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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