

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

: Effects of Blood Flow Restriction Exercises on Strength and Thickness of Supraspinatus Muscle and Level of Shoulder Pain at the Patients with Sub Acute Tendinopathy

Protocol summary

Study aim

to determine amount of effectiveness of Low load exercise with Blood Flow Restriction exercises on strength of stabilizer muscle of scapula and thickness and strength of supraspinatus muscle

Design

A concealed ,randomized, blinded , sham controlled clinical trial with parallel group design of 30 patient . The randomization sequence carried out with envelop

Settings and conduct

Subject: The effect of exercise therapy with Blood Flow Restriction on supraspinatus tendinopathy Location: Rehabilitation School Laboratory How to do the study: 1 - Check the entry conditions 2 - Patients enter the control and intervention group based on the envelope method 3- Determining the following items in the first session 1- Strength of middle and lower trapezius muscles and serratus anterior and supraspinatus using fixed dynamometer 2- Supraspinatus muscle thickness using ultrasound device 3- The threshold of compressive pain in the middle of the supraspinatus and deltoid bulk 4- The amount of 1RM using Brzycki formula and calculating 15 to 40% of it 5- Cuff pressure based on 50-80% of Limb Occlusion Pressure Exercise therapy protocol: 4 weeks (three days a week) Blinding method: Researcher blinding: Using another therapist Patient blinding: Using the same cuff with minimal pressure After 4 weeks, the evaluations of the first session are repeated. Determining the amount of pain in each session based on Pain Numeric scale

Participants/Inclusion and exclusion criteria

Inclusion criteria are patient with history of shoulder pain with age limit 30-65 & exclusion criteria are all factors that Blood Flow Restriction is contraindicated for them

Intervention groups

The intervention in intervention group is low load exercises with Blood Flow Restriction and the

intervention in control group is low load exercises

Main outcome variables

changes in muscle strength and thickness , pain

General information

Reason for update

Acronym

BFR

IRCT registration information

IRCT registration number: **IRCT20210210050317N1**

Registration date: **2021-04-01, 1400/01/12**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-01, 1400/01/12**

Update count: **0**

Registration date

2021-04-01, 1400/01/12

Registrant information

Name

Zahra Poursaleh Begi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2244 6831

Email address

poursalehzahra@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-27, 1399/11/08

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
: Effects of Blood Flow Restriction Exercises on Strength and Thickness of Supraspinatus Muscle and Level of Shoulder Pain at the Patients with Sub Acute Tendinopathy

Public title
the effect of Blood Flow Restriction Exercises on tendinopathy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
male and female with age limit 30-65 years old that have shoulder pain at least 1,5 month ago and at most 3 month ago the patient should have at least Positive 2 tests of these test: Painful Arch, Full Can, Empty Can and Hawkins patient that refer from orthopedic Doctors with sign and symptom of supraspinatus thendinopathy or if the patient have any evidence for tendinopathy with ultrasound and MRI
Exclusion criteria:
All contraindications of BFR(Blood Flow Restriction) , including history of blood clots, hypertension above 100/180, acute infection, peripheral vascular problems and varicose veins, cancer, Hemorrhagic or Thrombotic stroke, history of DVT(Deep Veins Thrombosis), Arterial fibrillation. Body Mass Index over 30 People taking medication for high blood pressure and blood sugar. People with a history of surgery, fractures or osteoarthritis in the shoulder area People who are suspected of having symptoms of COVID 19, such as fever, cough, runny nose, etc.

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done using the envelope method in such a way that 30 envelopes are prepared and 15 numbers 1 (control group) and 15 numbers 2 (intervention group) are written on paper and placed inside the envelopes, after the sequence of envelopes is mixed, to select an envelope, all the envelopes are

placed on the table to select them. After selecting the patient, the desired envelope is separated from the envelopes. This method is repeated for all patients. For the last patient, due to the fact that one envelope remains and according to the effect of the choice of others on the number of this envelope, a random state is maintained.

Blinding (investigator's opinion)

Double blinded

Blinding description

for blinding the researcher we will use another therapist for treatment in control and intervention group . patient blinding also will be doing with BFR cuff with minimal pressure

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

No. 8, Block 14, Entrance One, Nasr Alley, Nasr St , Shahid Mahallati Town , Aghdasiyeh Ave, Tehran

City

Tehran

Province

Tehran

Postal code

1955743494

Approval date

2021-01-23, 1399/11/04

Ethics committee reference number

IR.TUMS.FNM.REC.1399.185

Health conditions studied

1

Description of health condition studied

Sub-acute Supraspinatus Tendinopathy

ICD-10 code

M75.80

ICD-10 code description

Other shoulder lesions, unspecified shoulder

Primary outcomes

1

Description

Supraspinatus strength

Timepoint

measurement of supraspinatus strength will do in first session and after 12 session (4 month later ,tree time a week)

Method of measurement

the approach of measurement the strength is using fixed Dynamometer

2

Description

Serratus - Anterior Strength

Timepoint

measurement of serratus anterior strength will do in first session and after 12 session (4 month later ,tree time a week)

Method of measurement

the approach of measurement the strength is using fixed Dynamometer

3

Description

middle and lower trapezius strength

Timepoint

measurement of Strength of Middle and Lower Trapezius Muscle will do in first session and after 12 session (4 month later ,tree time a week)

Method of measurement

the approach of measurement the strength is using fixed Dynamometer

4

Description

Supraspinatus Strength

Timepoint

measurment of supraspinatus thickness will do in first session and after 12 session (4 month later ,tree time a week)

Method of measurement

the approach of measurement the thickness is using Ultrasound devise

5

Description

Pain Pressure Threshold

Timepoint

measurement of pain pressure threshold will do in first session and after 12 session (4 month later ,tree time a week)

Method of measurement

the approach of measurement the Pain Pressure Threshold is using Algometer

6

Description

Pain Report in every session based on Pain Numeric Scale Approach

Timepoint

measurement the amount of pain will do at before and after of every session

Method of measurement

the approach of measurement the Pain is using Pain Numeric Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Using low load exercises with blood flow restriction device using strength training protocol in such a way that in the upper limb 50% of the pressure that causes the pulse to be cut is used and in the lower limb 80% of this pressure is used. The sports version is in 4 sets with 30 repetitions in the first set and 15 times in the other three sets. Exercises with low load (15-40% of the maximum weight that a person can lift once). The device used is the standard model of the blood flow restriction device, which has vascular Doppler, which has the Smart Tools brand from the United States.

Category

Rehabilitation

2

Description

Control group: Exercises with low load using the cuff of the same device with minimal pressure to prevent the effects of placebo. The number of repetitions and sets as well as the amount of exercise load is similar to the intervention group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Science ,School of rehabilitation

Full name of responsible person

Zahra Poursaleh Begi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Sahrayyian

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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

Zahra Poursaleh Begi

Position

Physiotherapist

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Position

Master of science Student

Latest degree

Bachelor

Other areas of specialty/work

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no additional information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available