

# 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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No. 8, Block 1, Entrance One, Nasr Alley, Nasr St ,  
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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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## Person responsible for scientific inquiries

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**Position**

Master of science Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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## Person responsible for updating data

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Tehran University of Medical Sciences

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**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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**Email**

## **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