

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of blood flow restriction training and routine physical therapy on clinical outcomes in patients with lateral epicondylitis

#### Protocol summary

##### Study aim

This study aims to compare the effects of blood flow restriction training and routine physical therapy on clinical and functional outcomes in patients with lateral epicondylitis.

##### Design

Parallel groups randomized clinical trial with blinded outcome assessment

##### Settings and conduct

This clinical trial is conducted at Wasim General & Orthopaedic Hospital Gojra. The patients in control group have received routine physical therapy treatment including application of TENS, moist heat pad and stretching exercises (06 reps with 10 secs hold) and strengthening exercises (10 reps with 10 secs of resistance application). The patients in experimental group have received blood flow restriction resistance training in addition to routine physical therapy treatment. In this training, limb occlusion pressure (LOP) is measured of affected upper limb. BP cuff is applied at deltoid level to restrict the blood flow at 30% LOP and then patient is asked to perform resistance exercises in 04 sets with 30 reps in 1st set and 15 reps in other 03 sets. Each participant (of both group) has 03 session per week for 06 weeks. Only data assessor is blinded.

##### Participants/Inclusion and exclusion criteria

Patients of both genders having diagnosed unilateral tennis elbow in 20-50 years of age are included in the study. Patients who received steroid injections for tennis elbow in last 06 months, patients having cardiovascular diseases, bleeding disorders, peripheral diseases, hypertension, hypotension, tumor, trauma, systematic or skin diseases are excluded from the study.

##### Intervention groups

There are two intervention groups. The control group is receiving routine physical therapy treatment alone and experimental group is receiving blood flow restriction training along with routine physical therapy treatment.

##### Main outcome variables

The study outcome variables are pain, range of motion, functional disability and quality of life.

#### General information

##### Reason for update

To update contact information

##### Acronym

BRF Training

##### IRCT registration information

IRCT registration number: **IRCT20220904055878N1**

Registration date: **2022-11-30, 1401/09/09**

Registration timing: **retrospective**

Last update: **2024-03-04, 1402/12/14**

Update count: **1**

##### Registration date

2022-11-30, 1401/09/09

##### Registrant information

###### Name

Syeda Ambrin Naz

###### Name of organization / entity

.

###### Country

Pakistan

###### Phone

+92 305 6389206

###### Email address

msptm02183017@student.uol.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-01, 1401/03/11

##### Expected recruitment end date

2022-07-31, 1401/05/09

##### Actual recruitment start date

2022-07-18, 1401/04/27

**Actual recruitment end date**

2022-08-20, 1401/05/29

**Trial completion date**

2022-10-20, 1401/07/28

**Scientific title**

Effects of blood flow restriction training and routine physical therapy on clinical outcomes in patients with lateral epicondylitis

**Public title**

Blood Flow Restriction Training Treatment in Tennis Elbow

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients diagnosed with unilateral tennis elbow 20-50 years of age among both genders

**Exclusion criteria:**

Patients who received steroid injections for tennis elbow in last 06 months Cardiovascular diseases Bleeding disorders and peripheral vascular diseases History of hypertension or hypotension Tumor Trauma Systematic diseases Skin diseases

**Age**

From **20 years** old to **50 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **72**

Actual sample size reached: **72**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Concealed envelopes were used for the randomization of the participants into intervention and control groups

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The assessor and data analyzer are blinded by labelling the experimental and control groups with unidentifying symbols

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**

Research Ethics Committee The University of Lahore

**Street address**

1-Km Defence Road, near Bhuptian Chowk, Lahore, Punjab, Pakistan

**City**

Lahore

**Postal code**

54590

**Approval date**

2022-07-18, 1401/04/27

**Ethics committee reference number**

REC-UOL-/174-07/2022

## Health conditions studied

1

**Description of health condition studied**

The Lateral Epicondylitis (Tennis Elbow)

**ICD-10 code**

M77.1

**ICD-10 code description**

Tennis Elbow, Lateral Epicondylitis, Blood Flow Restriction Training Treatment

## Primary outcomes

1

**Description**

Pain

**Timepoint**

At the baseline, at the end of 3rd week, at the end of 6th week

**Method of measurement**

Visual Analogue Pain Scale

2

**Description**

Ranges of Motion (including wrist flexion, wrist extension, supination, pronation and elbow flexion)

**Timepoint**

At baseline, at the end of 3rd week and at the end of 6th week

**Method of measurement**

Goniometer

3

**Description**

Functional Disability

**Timepoint**

At the baseline, at the end of 3rd week and at the end of 6th week

**Method of measurement**

#### 4

##### **Description**

Quality of Life

##### **Timepoint**

At the baseline, at the end of 3rd week and at the end of 6th week

##### **Method of measurement**

36- Item Short Form Survey (SF-36)

#### **Secondary outcomes**

empty

#### **Intervention groups**

#### 1

##### **Description**

Control group: Routine Physical Therapy Treatment

##### **Category**

Rehabilitation

#### 2

##### **Description**

Intervention group: Blood Flow Restriction Training along with Routine Physical Therapy Treatment

##### **Category**

Rehabilitation

#### **Recruitment centers**

#### 1

##### **Recruitment center**

###### **Name of recruitment center**

Wasim General & Orthopedic Hospital

###### **Full name of responsible person**

Dr. Syeda Ambrin Naz

###### **Street address**

Jhang Road, Gojra

###### **City**

Gojra

###### **Postal code**

56000

###### **Phone**

+92 305 6389206

###### **Email**

ambrinambr@gmail.com

#### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

The University of Lahore

###### **Full name of responsible person**

Awais Raouf (Chairman of University of Lahore)

##### **Street address**

1-Km Defence Road, near Bhuptian Chowk, Lahore

##### **City**

Lahore

##### **Postal code**

54590

##### **Phone**

+92 42 111 865 865

##### **Email**

info@uol.edu.pk

##### **Grant name**

The University of Lahore

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

The University of Lahore

##### **Proportion provided by this source**

100

##### **Public or private sector**

Private

##### **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**

The University of Lahore

###### **Full name of responsible person**

Syeda Ambrin Naz

###### **Position**

Student

###### **Latest degree**

Medical doctor

###### **Other areas of specialty/work**

Physiotherapy

###### **Street address**

House P-24, Street- 03, Muhammad Pura, near Usman Town

###### **City**

Gojra

###### **Province**

Punjab

###### **Postal code**

56000

###### **Phone**

+92 305 6389206

###### **Email**

ambrinambr@gmail.com

#### **Person responsible for scientific inquiries**

##### **Contact**

###### **Name of organization / entity**

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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