Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 with10 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 envelops 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

Patient Rated Tennis Elbow Evaluation Questionnaire

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
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Gojra
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56000
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+92 305 6389206
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ambrinambr@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Lahore
Full name of responsible person
Awais Raoof (Chairman of University of Lahore)
Street address
1-Km Defence Road, near Bhuptian Chowk, Lahore
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+92 42 111 865 865
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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
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Person responsible for updating data

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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