

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Extra Corporeal Shock Wave Therapy versus Ultrasonic Therapy and deep friction massage in the management of Lateral Epicondylitis.

Protocol summary

Study aim

The aim is to study and compare the effects of shockwave therapy versus ultrasonic therapy and deep friction massage in patients with tennis elbow.

Design

Double Blind Parallel Arm Study. Randomized Clinical Trial.

Settings and conduct

This double blind (patient and outcome assessor will be blinded) parallel assignment study will be conducted in approximately one year at 2 settings; 1- Physiotherapy Department Syed Medical Complex, Sialkot Pakistan. 2- Physiotherapy Department Sialkot College of Physical Therapy, Amin Welfare & Teaching Hospital, Sialkot Pakistan.

Participants/Inclusion and exclusion criteria

Both male and female patients of 30-60 years of age with pain in twisting and turning movements of forearm. Patients with any history of trauma, surgery or presence of metal implant in elbow complex region, neurological deficits, radiculopathies and sensory impairments will be excluded.

Intervention groups

Group-A will be receiving shockwave therapy, Group-B will be administered Ultrasonic Therapy along with deep friction massage.

Main outcome variables

Patient Rated Tennis Elbow Evaluation Questionnaire and NPRS

General information

Reason for update

Trial completed. we included special test, which we used while enrolling the patients and finding their eligibility to be included in the trial. The randomization is not changed but the control group was also another intervention that's why we want to update it as randomized clinical trial instead of randomized control

trial.

Acronym

SWT

IRCT registration information

IRCT registration number: **IRCT20201031049207N4**

Registration date: **2020-12-25, 1399/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-31, 1402/05/09**

Update count: **2**

Registration date

2020-12-25, 1399/10/05

Registrant information

Name

Wajida Perveen

Name of organization / entity

Sialkot college of Physical Therapy, Amin Welfare & Teaching Hospital, defence Road, Sialkot Pakistan

Country

Pakistan

Phone

+92 52 3250520

Email address

drwajidaperveenpt@scptamc.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-15, 1399/09/25

Expected recruitment end date

2021-05-14, 1400/02/24

Actual recruitment start date

2020-12-15, 1399/09/25

Actual recruitment end date

2021-12-20, 1400/09/29

Trial completion date

2022-02-23, 1400/12/04

Scientific title

Effects of Extra Corporeal Shock Wave Therapy versus Ultrasonic Therapy and deep friction massage in the management of Lateral Epicondylitis.

Public title

Shockwave Therapy in Tennis Elbow

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Both Males and Females. Age between 30-60 years. pain in twisting and turning movements of forearm. Difficulty in holding weight in the affected side and walk. Range of wrist extension complete but painful Strength of extensor muscles Grade-IV Positive Mill's test. Positive Cozen's test

Exclusion criteria:

History of trauma in the region of Elbow complex. Presence of any metal implant. Any Neurological Deficits on the treatment sides Symptoms of Cervical Radiculopathies. Any sensory deficits. strength of extensors less than Grade-IV

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **74**

More than 1 sample in each individual

Number of samples in each individual: **1**

Any patient may have a bilateral problem.

Actual sample size reached: **74**

More than 1 sample in each individual

Actual sample size in each individual: **1**

Any patient may have a bilateral problem.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups. In Group A (Experimental group) patients will have shock wave treatment and in patients Group B (Experimental group) will have ultrasonic therapy and deep friction massage using coin toss method and allocation sequence will be concealed through sealed envelopes. Concealment of allocation: will be achieved with sequentially numbered, opaque, sealed, envelopes (SNOSE). SNOSE will be used according to guidelines of Doig and Simpson (25). An independent researcher with no clinical involvement in the trial will make the concealed envelopes. 60

Envelopes will be prepared. Half envelopes will contain folded papers with Treatment A written on them and the remaining half will contain folded papers with Treatment B written on them. A carbon paper will be inserted in each envelop with carbon side facing the paper so the allocation sequence, patient name, date of birth of

participant and other information can be transferred onto allocation paper inside the envelope. A piece of tin foil is also inserted into envelop so the treatment card cannot be read against light. Envelops will be sealed and signed by the maker. A unique randomized number will be allocated to these envelopes and shuffled vigorously. Then the envelopes will be arranged sequentially and handed over to another independent researcher. Assessor will pretest the participant and if eligible envelope will be allocated to subject. Therapist will record the information on the envelope and open it afterwards to maintain the concealment. Assessor will record the post treatment findings and another independent analyst will analyze the data. This allocation of concealment will ensure the unpredictability of treatment allocation by investigators and patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

In these patients assessor will be blinded to allocation of treatment groups in this study. Patient will be blinded to treatment allocation as treatment will be given in separate rooms for each group. Therapist who is not blinded will not take the outcome measurements.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

SCPT-IRB

Street address

Umer Street

City

Sialkot

Postal code

51310

Approval date

2020-11-16, 1399/08/26

Ethics committee reference number

IRB-SCPT-DPT-140-2020

Health conditions studied**1****Description of health condition studied**

Lateral Epicondylitis or Tennis Elbow

ICD-10 code

M77.10

ICD-10 code description

Lateral epicondylitis, unspecified elbow

Primary outcomes

1

Description

Patient Rated Tennis Elbow Evaluation

Timepoint

one Pre-Treatment, one after 3rd visit and 3rd after 7th visit

Method of measurement

subjective assessment of the patient

2

Description

Pain

Timepoint

before 1st treatment session, after 3rd treatment session and after 7th session

Method of measurement

Numeric Pain Rating scale

Secondary outcomes

1

Description

Quality of Life

Timepoint

before 1st treatment session and after last treatment session

Method of measurement

questionnaire SF-36

Intervention groups

1

Description

Intervention group: Group-A shock wave therapy group will be administered shockwave therapy with decompression on lateral side of elbow, with frequency 1Hz, energy level 2.0, for 7 sessions with gap of 4 days in each session.

Category

Treatment - Devices

2

Description

Intervention group: Group-B Ultrasonic therapy and deep friction massage group. patients will be provided with ultrasonic therapy 2.5w/sec² (intermittent) 3 times a week for four weeks. deep friction massage will be an adjunct to ultrasonic therapy.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Department Syed Medical Complex.

Full name of responsible person

Riaz Hashmi

Street address

Commissioner Road

City

Sialkot

Postal code

51310

Phone

+92 52 4598056

Email

riazhashmiphysio@gmail.com

Web page address

https://web.facebook.com/syedmedicalcomplex/?_rdc=1&_rdr

2

Recruitment center

Name of recruitment center

Physiotherapy Department, Sialkot College of Physical Therapy, Amin Welfare & Teaching Hospital

Full name of responsible person

Wajida Perveen

Street address

Umer Street

City

Sialkot

Postal code

51310

Phone

+92 52 3250520

Email

wjda_noor@yahoo.com

Web page address

<http://www.scptamc.com/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

None

Full name of responsible person

none

Street address

Umer Street

City

Sialkot

Postal code

51310

Phone

+92 52 3250520

Email

info@scptamc.com

Grant name

Grant code / Reference number

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

No

Title of funding source

none

Proportion provided by this source

1

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**

Other

Person responsible for general inquiries**Contact****Name of organization / entity**

Sialkot College of Physical Therapy

Full name of responsible person

Wajida Perveen

Position

Associate Professor/ Incharge Physiotherapy

Department

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Umer Street

City

Sialkot

Province

Punjab

Postal code

51310

Phone

+92 52 3250520

Email

wjda_noor@yahoo.com

Web page addresshttps://www.researchgate.net/profile/Wajida_Perveen**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Syed Medical Complex

Full name of responsible person

Riaz Hashmi

Position

Incharge Physical Therapy Department

Latest degree

Specialist

Other areas of specialty/work

Physiotherapy

Street address

Commissioner Road

City

Sialkot

Province

Punjab

Postal code

51310

Phone

+92 52 4598056

Email

riazhashmiphysio@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Sialkot College of Physical Therapy, Amin Welfare & Teaching Hospital

Full name of responsible person

Wajida Perveen

Position

Associate Professor/ HOD

Latest degree

Specialist

Other areas of specialty/work

Physiotherapy

Street address

Umer Street

City

Sialkot

Province

Punjab

Postal code

51310

Phone

+92 52 3250520

Email

wjda_noor@yahoo.com

Web page addresshttps://www.researchgate.net/profile/Wajida_Perveen**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 further information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Effects of Shockwave therapy versus ultrasonic and deep friction massage in the management of Lateral Epicondylitis. outcomes of the effects of treatment

modality will be shared after completion of the study.

When the data will become available and for how long

after completion of study (January 2022).

To whom data/document is available

further information can be requested to principal investigator by those who are working in academic institutions and are interested to apply extra corporeal shockwave in tennis elbow.

Under which criteria data/document could be used

the data may be used as a reference after the study has been completed and published. Principal investigator will review the requests himself on predefined review criteria

and respond accordingly.

From where data/document is obtainable

Any applicant can contact Principle investigator/ person responsible for scientific inquiries via email to request the sharing of data.

What processes are involved for a request to access data/document

The data can be accessed by direct request via email to the Principal investigator/ person responsible for scientific inquiries. He will respond in 10 working days positively.

Comments