

# 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/sec<sup>2</sup> (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](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 address**[https://www.researchgate.net/profile/Wajida\\_Perveen](https://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**

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**Postal code**

51310

**Phone**

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**Email**

riazhashmiphysio@gmail.com

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

Sialkot College of Physical Therapy, Amin Welfare &amp; 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 address**[https://www.researchgate.net/profile/Wajida\\_Perveen](https://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**