Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of Extra Corporeal Shock Wave Therapy versus Ultrasonic Therapy and deep friction message 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 message 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 envelops 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 envelops and shuffled vigorously. Then the envelops 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 address
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
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 address
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