

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### **Effectiveness of high-energy extracorporeal shockwave therapy along with routine physical therapy on subjective and objective measures in patients with calcified rotator cuff tendinopathy; a randomized controlled trial**

#### **Protocol summary**

##### **Study aim**

1. To determine the effectiveness of high-energy extracorporeal shockwave therapy along with routine physical therapy on pain intensity, range of motion, functional activity and radiological outcomes in patients with calcified rotator cuff tendinopathy.

##### **Design**

Parallel group, single blinded, randomized controlled trial

##### **Settings and conduct**

Physiotherapy department, Lifeline Health Care and Pain Centre, Lahore Pakistan

##### **Participants/Inclusion and exclusion criteria**

Inclusion Criteria:  Patients with calcified rotator cuff tendinopathy referred by orthopedic surgeons or rheumatologists  Either gender, age ranges from 30-55 years  Radiological evidence of type A or B calcification ( $\geq 1\text{cm}$  or  $10\text{mm}$ ) Exclusion Criteria: • Patients having primary joint trauma or infection in shoulder region • Frozen shoulder or symptoms from cervical spine, glenohumeral osteoarthritis • Shoulder instabilities, malignancies and nerve injuries

##### **Intervention groups**

Randomly, treatment will be assigned to patients in this study. Group-A (Experimental group): It will receive routine physical therapy treatment and high-energy extra-corporeal shockwave therapy. Routine physiotherapy treatment will be administered to the patients. Group B (Control group): In this group, routine physical therapy will be given to treat calcified tendinopathy. For routine treatment, same interventions will be administered to the patients as given to group A.

##### **Main outcome variables**

Numeric Pain Rating Scale Constant and Murley Score  
Western Ontario Rotator Cuff Index Radiological outcomes

#### **General information**

##### **Reason for update**

##### **Acronym**

CRCTT

##### **IRCT registration information**

IRCT registration number: **IRCT20200204046373N1**  
Registration date: **2020-03-28, 1399/01/09**  
Registration timing: **prospective**

Last update: **2020-03-28, 1399/01/09**

Update count: **0**

##### **Registration date**

2020-03-28, 1399/01/09

##### **Registrant information**

##### **Name**

Arooj Fatima

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

The University Of Lahore

##### **Country**

Pakistan

##### **Phone**

+92 42 35414221

##### **Email address**

aruj43@hotmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2020-04-10, 1399/01/22

##### **Expected recruitment end date**

2020-09-30, 1399/07/09

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

**Trial completion date**  
empty

**Scientific title**  
Effectiveness of high-energy extracorporeal shockwave therapy along with routine physical therapy on subjective and objective measures in patients with calcified rotator cuff tendinopathy; a randomized controlled trial

**Public title**  
High-energy extracorporeal shockwave therapy in patients with calcified rotator cuff tendinopathy

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with calcified rotator cuff tendinopathy referred by orthopedic surgeons or rheumatologists of either gender, age ranges from 30-55 years □ Having at least 3 months history of shoulder pain located in the proximal lateral aspect of the upper arm Radiological evidence of type A or B calcification (≥1cm or 10mm) 2 of 3 impingement test positive - Neer's test, Hawkins tests and/or Jobe test  
**Exclusion criteria:**  
Patients having primary joint trauma or infection in shoulder region • Frozen shoulder or symptoms from cervical spine, glenohumeral osteoarthritis History of Shoulder instabilities, malignancies and nerve injuries, Chronic diabetic patients, diabetic neuropathy Patients with metallic implant, Pregnant female, Severe renal or cardiovascular diseases Patients having clotting disorders or having anticoagulant treatment History of any fracture or surgery in the shoulder complex or Full thickness rupture in the rotator cuff tendon

**Age**  
From **30 years** old to **55 years** old

**Gender**  
Both

**Phase**  
2

**Groups that have been masked**

- Outcome assessor

**Sample size**  
Target sample size: **48**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The patients having diagnosed calcified rotator cuff tendinopathy will be recruited in the study by convenient sampling, and the patients who fulfilled the inclusion and exclusion criteria will be selected, with similar baseline characteristics. The consent will be taken from the subjects to participate in the study. It will be a single blinded trial in which the assessor will be kept blind. The subjects will be randomly assigned to one of two groups by using a table of random numbers generated the randomization sequence, using a restricted randomization scheme to assure equal numbers in each group. Random allocation to all groups will be ensured,

from all study personnel and participants by entry of data into computer randomization program immediately.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
It will be a single blinded trial in which the assessor will be kept blind. Assessor will be senior physiotherapist who will take measurements after giving consent to participate in study. He will be blind; not confirmed about the group of intervention

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
Parallel groups, single blinded, single setting

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**  
**Name of ethics committee**  
Institutional Review Board Committee  
**Street address**  
1 km, Bhabatyan chowk, Raiwind road  
**City**  
Lahore  
**Postal code**  
0544  
**Approval date**  
2641-06-20, 2020/03/30  
**Ethics committee reference number**  
IRB-UOL-FAHS/693/2020

**Health conditions studied**

1

**Description of health condition studied**  
Rotator cuff tendinopathy  
**ICD-10 code**  
M75  
**ICD-10 code description**  
Shoulder lesions

**Primary outcomes**

1

**Description**  
Pain intensity  
**Timepoint**  
Baseline, 6th and 12th week  
**Method of measurement**  
Numeric Pain Rating Scale

## Secondary outcomes

1

### Description

Functional mobility

### Timepoint

Baseline, 6 and 12 week

### Method of measurement

Constant and Murley score

## Intervention groups

1

### Description

Intervention group: Shockwave therapy along with routine physical therapy. It will receive routine physical therapy treatment and high-energy extra-corporeal shockwave therapy. Routine physiotherapy treatment will be administered to the patients which includes these:

- General exercise plan (range of motion, strengthening, and stretching exercises of shoulder abductors and flexors). Each exercise will be performed once a day with ten repetitions, three times a week.<sup>32</sup>
- Advice rest, avoiding overuse or heavy weight lifting

### Category

Treatment - Devices

2

### Description

Control group: It will be give same routine treatment methods given generally to treat such patients for same time

### Category

Treatment - Devices

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Physiotherapy department, Lifeline Health Care and Pain Centre, Lahore Pakistan

#### Full name of responsible person

Tehreem Niazi

#### Street address

Johar town

#### City

Lahore

#### Postal code

0544

#### Phone

#### Email

tehreemkhan.tk@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

University of Lahore

#### Full name of responsible person

Ashfaq Ahmad

#### Street address

1 km, Raiwind road

#### City

Lahore

#### Postal code

0544

#### Phone

#### Email

ashfaaqpt@gmail.com

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

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

University of Lahore

#### Full name of responsible person

Arooj Fatima

#### Position

Assistant Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Physiotherapy

#### Street address

1 km, Raiwind road

#### City

Lahore

#### Province

Punjab

#### Postal code

54000

#### Phone

+92 341 4391882

#### Email

aruj43@hotmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

University of Lahore

**Full name of responsible person**

Arooj Fatima

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

1 km, raiwind road

**City**

Lahore

**Province**

Punjab

**Postal code**

54000

**Phone**

0923414391882

**Email**

aruj43@hotmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

University of Lahore

**Full name of responsible person**

Arooj Fatima

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

1 km, raiwind road

**City**

Lahore

**Province**

Punjab

**Postal code**

54000

**Phone**

0923414391882

**Email**

aruj43@hotmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

all collected IPD for all outcome measures

**When the data will become available and for how long**

starting in November 2020 6 months after publication

**To whom data/document is available**

persons in academic institutes

**Under which criteria data/document could be used**

it could be used on request

**From where data/document is obtainable**

03414391882

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

can call or mail

**Comments**

data can be provided on request