

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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(≥ 1 cm or 10mm) 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 ($\geq 1\text{cm}$ 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, Bhobatiyan 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.³²
- 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

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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

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Position

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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