Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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(≥1cm 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 calcifies 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 ofeither 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, 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
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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
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Postal code
0544
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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
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Other areas of specialty/work
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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 bee provided on request