

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative effectiveness between pulsed and continuous mode of Ultrasound in knee osteoarthritis.

Protocol summary

Study aim

To determine the comparative effectiveness of pulse and continuous mode of therapeutic ultrasound in grade I & grade II osteoarthritis of knee joint in terms of pain, range of motion, activity level and functional independence.

Design

Randomised, double blinded, two phase study with two intervention groups observed at the same time.

Settings and conduct

Study is double blinded with participant and outcome assessor blinding. Study will be conducted in Mayo Hospital Lahore, Pakistan

Participants/Inclusion and exclusion criteria

Participants with age between 50 and 65 with diagnosed osteoarthritis of knee joint in grade 1 and grade 2 of Kellgen and Lawrence classification are included in the study. Participants with cancer, NSAIDS or thrombophlebitis are excluded from the study.

Intervention groups

There are two intervention groups. Continuous mode of ultrasound and Pulsed mode of ultrasound.

Main outcome variables

Pain, range of motion, activity level and functional independence.

General information

Reason for update

Acronym

OA (Osteoarthritis)

IRCT registration information

IRCT registration number: **IRCT20220513054841N1**

Registration date: **2023-05-19, 1402/02/29**

Registration timing: **prospective**

Last update: **2023-05-19, 1402/02/29**

Update count: **0**

Registration date

2023-05-19, 1402/02/29

Registrant information

Name

Maheen Shad

Name of organization / entity

King Edward Medical University, Mayo Hospital
Lahore, Pakistan

Country

Pakistan

Phone

+92 334 4177821

Email address

maheen.shad_25@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-30, 1402/03/09

Expected recruitment end date

2023-12-30, 1402/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effectiveness between pulsed and continuous mode of Ultrasound in knee osteoarthritis.

Public title

Ultrasound effectiveness in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 50 and 65 Grade I & II osteoarthritis of

knee (Kellgen & Lawrence) Osteoarthritic diagnosed patients with complaints of pain and functional disability for at least three months

Exclusion criteria:

Lower extremity cement or plastic implants
Local dermatological problem e.g. psoriasis and eczema
Thrombophlebitis or any vascular condition in which ultrasound can cause breakage of emboli
Cancer
Pregnancy
Patients using anti-inflammatory medications

Age

From **50 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 60 patients are included in this study. They have been randomized through a system generated software into two groups A and B. Randomization process is concealed from the patients and the practitioner. Computer software generated two lists dividing all the patients into two treatment groups randomly.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants were allocated in two treatment groups named as A and B. None of the participants know which of the two modes of ultrasound has been used on him/her as both modes require the ultrasound machinery and nothing else. Care provider has been giving treatment according to the protocols decided and he/she has no role in measuring the results. Outcome assessor or the investigator is involved in the outcome measurements of both groups and has no role in applying treatment protocols of the patients or the randomization. Data analyser is involved in the analysis of data only and has no role in randomization, treatment application or outcome measurement. None of the members of DSMB are involved in the application of randomization, treatment application, outcome measurement or the data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of King Edward Medical University, Lahore Pakistan

Street address

Nila Gumbad Chowk, Neela Gumbad Lahore, Punjab, Pakistan

City

Lahore

Postal code

54000

Approval date

2022-04-27, 1401/02/07

Ethics committee reference number

5641/RE/KEMU/2022

Health conditions studied

1

Description of health condition studied

Osteoarthritis of knee joint diagnosed with grade I and grade II of Kellgen and Lawrence classification of knee joint osteoarthritis.

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Pain

Timepoint

Before intervention and 2, 4 weeks after intervention

Method of measurement

Visual Analogue Scale

2

Description

Range of motion of knee joint

Timepoint

Before intervention and 2, 4 weeks after intervention

Method of measurement

Goniometer

3

Description

Activity level

Timepoint

Before intervention and 2 ,4 weeks after intervention
Method of measurement
Western Ontario and McMaster Universities Arthritis Index.WOMAC

4

Description
Functionality
Timepoint
Before intervention and 2 ,4 weeks after intervention
Method of measurement
Lequesne Index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Continuous mode of ultrasound
Category
Rehabilitation

2

Description
Intervention group: Pulsed mode of ultrasound
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
King Edward Medical University, Mayo Hospital,
Lahore Pakistan
Full name of responsible person
Maheen Shad
Street address
Nila Gumbad Chowk, Neela Gumbad Lahore, Punjab
54000
City
Lahore
Postal code
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Phone
+92 334 4177821
Email
maheenshad25@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

King Edward Medical University, Mayo Hospital Lahore
Full name of responsible person
Maheen Shad
Street address
Nila Gumbad Chowk, Neela Gumbad Lahore, Punjab
54000
City
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Phone
+92 334 4177821
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maheenshad25@gmail.com

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
King Edward Medical University, Mayo Hospital Lahore
Proportion provided by this source
100
Public or private sector
Public
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
King Edward Medical University, Mayo Hospital Lahore
Full name of responsible person
Maheen Shad
Position
Post Graduate Resident
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
Nila Gumbad Chowk, Neela Gumbad Lahore, Punjab
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City
Lahore
Province
Punjab
Postal code
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Phone
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maheenshad25@gmail.com

Person responsible for scientific inquiries

Contact

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data will be shared in the form of excel and Microsoft word files.

When the data will become available and for how long

6 months after publication

To whom data/document is available

Only available for people working in academic institutions

Under which criteria data/document could be used

Person responsible for data update will be reviewing requests for data. Data will be shared through email.

From where data/document is obtainable

maheenshad25@gmail.com

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

Provide full detail of the reason you want to pursue data from my study. Then wait for a max of one month to receive it if the request for data is approved.

Comments

Person responsible for updating data

Contact

Name of organization / entity

King Edward Medical University, Mayo Hospital Lahore

Full name of responsible person

Maheen Shad

Position

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Latest degree

Master

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