Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 in 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 participant 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 appliaction or outcome measurement. None of the members of DSMB are involved in the appliaction 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 wit 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

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Phone

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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

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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

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Person responsible for scientific inquiries

Contact

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King Edward Medical University, Mayo Hospital Lahore

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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