

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effect Of Physiotherapy-Led Functional Exercise Regime vs. Conventional Therapy on Functional Outcomes After Total Hip Arthroplasty

Protocol summary

Study aim

The aim of the study is to add in the evidence of physical therapy protocols after the surgical procedure of Total Hip Arthroplasty.

Design

Randomized controlled trial, single-centered, concealed, two arm parallel group of 82 patients, with blinded outcome assessment

Settings and conduct

Settings- Mayo Hospital Lahore (Orthopedics and Physiotherapy Department) Blinded outcome assessor

Participants/Inclusion and exclusion criteria

Inclusion Criteria Age 30 to 60 years, Total hip arthroplasty, 1 to 16 weeks after THA, Able to understand instructions, Willing to come for all follow-ups, Exclusion Criteria Tumor / cancer, Total knee replacement, Revision arthroplasty surgery, Any underlying terminal disease, Suspicion of infection following joint replacement,

Intervention groups

Group A will receive Functional Exercise Protocol Group B will receive Conventional Exercises Protocol

Main outcome variables

Pain, stiffness, physical functioning, Health related quality of life,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220628055308N1**

Registration date: **2022-10-02, 1401/07/10**

Registration timing: **retrospective**

Last update: **2022-10-02, 1401/07/10**

Update count: **0**

Registration date

2022-10-02, 1401/07/10

Registrant information

Name

Dr. Samawiya Farooq

Name of organization / entity

King Edward Medical University, Lahore, Pakistan

Country

Pakistan

Phone

+92 334 5444098

Email address

samawiyafarooq@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-28, 1401/02/08

Expected recruitment end date

2022-08-31, 1401/06/09

Actual recruitment start date

2022-04-28, 1401/02/08

Actual recruitment end date

2022-08-24, 1401/06/02

Trial completion date

2022-08-26, 1401/06/04

Scientific title

Comparison of the Effect Of Physiotherapy-Led Functional Exercise Regime vs. Conventional Therapy on Functional Outcomes After Total Hip Arthroplasty

Public title

Functional Outcomes After Total Hip Arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 30 to 60 years Total hip arthroplasty 1 to 16 weeks after THA Able to understand instructions Willing to come for all follow-ups

Exclusion criteria:

Tumor / cancer Total knee replacement Revision arthroplasty surgery Any underlying terminal disease Suspicion of infection following joint replacement

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Actual sample size reached: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized Control Trial Computer generated table of random numbers The sample was simply randomized into two equal groups (1:1) by MS Excel. The patients were individually assigned group as per the randomization table generated. The randomization sequence was built by using a "Rand" function in MS Excel on the sample of 82 patients with equal distribution of 41 sample among the two groups. The "Rand" function can be used to generate random numbers. It will return a random number between 0 and 1. The syntax for the RAND function in Microsoft Excel is: RAND(). In 1st column of MS Excel spreadsheet, patient numbers were written i.e. 82 In the 2nd column, groups were written. In this study either it's a functional exercise/ group A or a conventional therapy group/ group B. The first 41 samples as functional exercise / group A and next 41 as conventional therapy group/ group B. In 3rd column, Randomization formula was added which is between 0-1 by Inserting a function called "Rand" in the first row of 3rd column. MS Excel has added a random number to the cell. The random number was then added in the entire column by dragging through the cells. Column 2 and column 3 were filtered in order to randomize column 2. After this column 3 was filtered in ascending order from the options of top row header to randomize it. All the content in column 2 were randomized. Likewise, all the patient numbers were randomized to either functional exercise/ group A or a conventional therapy group/ group B. The randomization table was generated by the other person and the group allotment of the participant was done by the other on the basis of concealed allocation. Allocation Concealment was carried out by sequentially numbered, opaque, sealed envelope (SNOSE) technique in which the randomization group were written on a paper and kept in an opaque sealed envelope. The envelope was labeled with a serial number. The investigator opens the sealed envelope once the patient has consented to participate and then assigns the treatment group accordingly.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

NA

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board, KEMU, Lahore

Street address

Neelagumbad, Anarkali, Lahore Pakistan

City

Lahore

Postal code

54000

Approval date

2022-02-08, 1400/11/19

Ethics committee reference number

300/RC/KEMU/2022 (12-02-2022)

Health conditions studied**1****Description of health condition studied**

Total Hip Arthroplasty

ICD-10 code

Z96.64

ICD-10 code description

Presence of artificial hip joint

Primary outcomes**1****Description**

Pain

Timepoint

Before Intervention and 6 Weeks After Intervention

Method of measurement

VAS & WOMAC pain score

2**Description**

Stiffness

Timepoint

Before Intervention and 6 Weeks After Intervention

Method of measurement

WOMAC Stiffness score

3

Description

Physical Functioning

Timepoint

Before Intervention and 6 Weeks After Intervention

Method of measurement

WOMAC Physical Functioning score

4

Description

Functional Outcomes

Timepoint

Before Intervention and 6 Weeks After Intervention

Method of measurement

WOMAC scores

5

Description

Health Related Quality of Life

Timepoint

Before Intervention and 6 Weeks After Intervention

Method of measurement

SF-12 Scores

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Functional Exercise (Those 41 participants randomized to the intervention group will receive functional exercise under the supervision of the physiotherapist. Each session will be of approximately 35 minutes in length with 10 repetitions for a given exercises. Patients will attend the session twice weekly for 6 weeks, and will be given same exercises as a home exercise program. The functional exercise program in this study will be based on the following exercise plan: Sit to stand, Toe raises, Knee raises, Side and back leg raises, Partial knee bends, Single knee bends, One legged standing balance and advanced one legged standing balance, Pelvic raising and lowering.)

Category

Rehabilitation

2

Description

Control group: Conventional Therapy Group (Those randomized to the Group B will receive the conventional therapy protocol under the supervision of the physiotherapist. Each session will be of 35 minutes in length with 10 repetitions for a given exercises. Patients will attend the session twice weekly for 6 weeks and will be given same exercises as a home exercise plan. This will include the following exercise plan: Foot and ankle

pumps, Static quadriceps contractions, Static gluteal contractions, Active hip flexion, Active hip extension, Active hip abduction, Hip external rotations and Hamstring Curls.)

Category

Rehabilitation

Recruitment centers

1

Recruitment center**Name of recruitment center**

Mayo Hospital Lahore, Pakistan

Full name of responsible person

Dr. Samawiya Farooq

Street address

Hospital Rd, Anarkali Bazaar Lahore, Punjab

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Phone

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Email

samawiyafarooq@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

King Edward Medical University, KEMU, Lahore, Pakistan

Full name of responsible person

Dr. Samawiya Farooq

Street address

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Grant name

No Grant Provided by the Institute

Grant code / Reference number

No Grant Provided by the Institute

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

Yes

Title of funding source

King Edward Medical University, KEMU, Lahore, Pakistan

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, KEMU, Lahore,
Pakistan

Full name of responsible person

Dr. Samawiya Farooq

Position

Post Graduate Resident- Trainee - M.Phil.
Physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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House Number 302, Opposite JCO Club, R.A.Bazaar,
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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Fax**Email**

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"There is no further information"

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

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

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

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

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Comparison of the Effect Of Physiotherapy-Led
Functional Exercise Regime vs. Conventional Therapy on
Functional Outcomes After Total Hip Arthroplasty

When the data will become available and for how long

Data will be available after publication of the study.

To whom data/document is available

Data will be available after publication of the study to

Clinical researchers and physiotherapists.

Under which criteria data/document could be used

It can be used to further research on the topic.

From where data/document is obtainable

Contact with the corresponding author will be required.

What processes are involved for a request to access

data/document

Process can be done through email and can take few days to respond.

Comments

NA