Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Pakistan
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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 though 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
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Hospital Rd, Anarkali Bazaar Lahore, Punjab
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Sponsors / Funding sources

1

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King Edward Medical University, KEMU, Lahore, Pakistan
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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
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Person responsible for updating data

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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