

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of Interferential current Therapy in addition to Routine Physical Therapy on Clinical and Physical Outcomes on Early postoperative Total Knee Arthroplasty

Protocol summary

Study aim

The aim of this study is to investigate the effectiveness of interferential current therapy on pain, edema, range of motion (ROM), basic functional mobility and knee stiffness in the early postoperative rehabilitation in total knee arthroplasty.

Design

Randomized Controlled Trial, After the synopsis is approved, the project will be conducted with in nine months, Non Probability Sampling Technique Sample Selection:

Settings and conduct

Study Setting: Bahria International Hospital, Lahore
Binding: The trial will be single-blinded because the assessor will not know which group will get treatment.
Assessment: Baseline and post-treatment information will be analyzed from each participant to determine the effectiveness of each treatment. After the week of treatment, a follow-up assessment will be conducted, and all results compared during treatment. A comparison of the pre-and post-treatment ranges also will be performed.

Participants/Inclusion and exclusion criteria

52 Participants included. Both male and female patients. Age between 45 to 65 years. Participants who has undergone total knee arthroplasty for the first time Patients who are not exposed to IFC treatment pre-operatively. Exclusion criteria: Patients with causes as: Infections, Deep Vein thrombosis(DVT), Cancer and Epilepsy. Bone and joint diseases or serious diseases affecting organ function. Any patient with pacemaker or any electrical stimulator device

Intervention groups

The experimental group used Interferential current therapy (IFC) in addition to conventional rehabilitation protocol. The control group received conventional rehabilitation training for the treatment of TKA. The same

therapist will be employed to conduct each treatment for 20 minutes, twice a day, 3 times a week, for total of 1 week

Main outcome variables

Outcome measures: Clinical and physical outcomes (Pain, Edema, ROM and Basic Functional Mobility)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231108059998N1**

Registration date: **2024-03-08, 1402/12/18**

Registration timing: **retrospective**

Last update: **2024-03-08, 1402/12/18**

Update count: **0**

Registration date

2024-03-08, 1402/12/18

Registrant information

Name

Aqsa Aziz

Name of organization / entity

University of lahore

Country

Pakistan

Phone

+92 331 8446171

Email address

aqsaaziz26@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-12-31, 1402/10/10

Actual recruitment start date

2023-06-10, 1402/03/20

Actual recruitment end date

2023-12-31, 1402/10/10

Trial completion date

2023-12-31, 1402/10/10

Scientific title

Effects of Interferential current Therapy in addition to Routine Physical Therapy on Clinical and Physical Outcomes on Early postoperative Total Knee Arthroplasty

Public title

Effects of Interferential Therapy in addition to Routine Physical Therapy on Clinical and Physical Outcomes on Early postoperative Total Knee Arthroplasty

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Both male and female patients. Age between 45 to 65 years. Patients who are not exposed to IFC treatment pre-operatively. Participants who has undergone total knee arthroplasty for the first time

Exclusion criteria:

Patients with causes as: Infections, Deep Vein thrombosis(DVT), Cancer and Epilepsy Bone and joint diseases or serious diseases affecting organ function. Any patient with pacemaker or any electrical stimulator device

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample size

Target sample size: **52**

Actual sample size reached: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

The scratch card method of randomization will be used to divide the participants into experimental groups at random. Each participant will be given a unique number. After that, each group will be assigned an arbitrary number of members.

Blinding (investigator's opinion)

Single blinded

Blinding description

The trial will be single-blinded because the assessor will not know which group will get treatment.

Placebo

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

Research Ethics committee- Faculty of Allied Health Sciences,The University of Lahore.

Street address

1-Km Defence Road., near Bhuptian Chowk., Lahore, Punjab

City

Lahore

Postal code

54590

Approval date

2023-11-30, 1402/09/09

Ethics committee reference number

Rec-UOL-651-01-2024

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

Early post-operative Rehabilitation for total knee arthroplasty patients unilaterally.

ICD-10 code

Z96-65

ICD-10 code description

Z96-65

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

Pain,Range of Motion,Edema and Basic Functional Mobility

Timepoint

Baseline and 1st week

Method of measurement

Pain - Faces Wong Baker Pain Rating Scale ,Range of Motion - Goniometer,Edema - Measuring Tape and AM-PAC 6 clicks in-patient questionnaire used for Basic Functional Mobility .

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention GroupA(IFC+Routine Physical Therapy) is exposed to Interferential Current therapy (Model

no:ES-522 ITO Physiotherapy Low and Medium Frequency Electrical Stimulation device) in addition to conventional physical therapy. .Conventional rehabilitation training group exercises including Routine physical therapy: Range of motion exercises, ankle pumps ,SLR-straight leg raise , knee iso-metrics , Quadriceps strengthening(knee press), heel press ,hamstring strengthening (clamshell)and partial to complete weight bearing in knee extension with knee immobilizer using walking aids . Walkers, knee supports like immobilizer will use to train the patient's body posture stepping and Gait training session will last for 20 minutes, twice a day,3 times a week for total of 1 week that is in-patient stay.

Category

Treatment - Devices

2

Description

Control GroupB(Routine Physical Therapy): Conventional rehabilitation training group exercises including Routine physical therapy: Range of motion exercises, ankle pumps ,SLR-straight leg raise , knee iso-metrics , Quadriceps strengthening(knee press), heel press ,hamstring strengthening (clamshell)and partial to complete weight bearing in knee extension with knee immobilizer using walking aids . Walkers, knee supports like immobilizer will use to train the patient's body posture stepping and Gait training session will last for 20 minutes, twice a day,3 times a week for total of 1 week that is in-patient stay.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahria International Hospitals Lahore .

Full name of responsible person

Dr.Hafiz Ammar Qayyum

Street address

Takbeer Block Sector B Bahria Town, Lahore, Punjab

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<https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://bahriainternationalhospital.com/%23:~:text=3DBahria%2520International%2520Hospital%2520Lahore%2520a,healthcare%2520provider%2520in%2520the%2520region.&ved=2ahUKEwi3jZK30IyEAXVN7QIHHCd-C1cQFnoECB4QBA&usg=AOvVaw1IUqm7gFfOJ52In9SI>

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University Of Lahore

Full name of responsible person

Dr Ayesha Jamil,Dr Aqsa Aziz

Street address

1-Km Defence Road,, near Bhuptian Chowk., Lahore, Punjab

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Web page address

https://www.google.com/url?sa=t&source=web&rct=j&opi=89978449&url=https://uol.edu.pk/contact-us/&ved=2ahUKEwikyeKp0oyEAXUR0wIHHcCXCsoQFnoECBwQAQ&usg=AOvVaw0-hG_bjJJYb7syMAmyXxUL

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

Aqsa Aziz

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Full name of responsible person

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Latest degree
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Other areas of specialty/work
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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

Due to Confidentiality and research ethics

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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