Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Pakistan
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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 immbolizier 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 immbolizier 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

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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=AOvVaw1lUqm7gFfOJ52In9Sl9a2z

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

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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

Contact
Name of organization / entity
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Student
Latest degree
Medical doctor
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