

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Influence of early hip muscles strengthening on physical function in patients with unilateral total knee arthroplasty

Protocol summary

Study aim

The aim of this study was to evaluate the effect of strengthening hip muscles on the patients' function after unilateral total knee arthroplasty.

Design

Clinical trials with control group, with parallel groups, without blindness, randomized

Settings and conduct

The study will be done in Rasool Akram Hospital and Shafa Yahyaiean Hospital and will be started 2 days after surgery and 3 times a week. There are two intervention and control groups that received both TENS and infrared radiation for 20 minutes, strengthening exercises of knee flexor and extensor muscles and range of motion exercises, and the intervention group received strengthening exercises of hip muscles from the fourth session. ten treatment sessions will be done for All subjects. Patients are asked to do each exercise three times a day and 10 repetitions each time.

Participants/Inclusion and exclusion criteria

inclusion criteria: unilateral total knee replacement
Indication of bicompartment prosthesis Cemented fixation
There is no problem or another surgery except joint replacement in the lower extremities that is limiting the function
Absence of cognitive impairment
Lack of abnormal blood pressure and uncontrolled diabetes
BMI less than 40
Not having another surgery program during this study
Lack of post-surgery complications including hemarthrosis, infection, fracture, wound impairment
No visual and auditory impairment
exclusion criteria: The occurrence of any problem in the implementation of the plan
Lack of patient willingness to continue cooperation
Incidence of deep venous thrombosis

Intervention groups

control group : Strengthening exercises of knee extensor and flexor muscles and range of motion exercises
intervention group: exercises of control group and strengthening exercises of hip muscles

Main outcome variables

Pain; range of motion; quality of life; function; strength of the knee and hip muscles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150314021459N6**

Registration date: **2018-12-26, 1397/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-26, 1397/10/05**

Update count: **0**

Registration date

2018-12-26, 1397/10/05

Registrant information

Name

Mohammad Akbari

Name of organization / entity

Dept. of Physical therapy, School of Rehabilitation, Iran University of Medical Sciences.

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 8051

Email address

akbari.mo@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-01, 1397/09/10

Expected recruitment end date

2019-01-30, 1397/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Influence of early hip muscles strengthening on physical function in patients with unilateral total knee arthroplasty

Public title

Influence of hip strengthening on function in patients with knee arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

unilateral total knee replacement Indication of bicompartement prothesis Cemented fixation There is no problem or another surgery except joint replacement in the lower extremities that is limiting the function
Absence of cognitive impairment Lack of abnormal blood pressure and uncontrolled diabetes BMI less than 40 Not having another surgery program during this study Lack of post-surgery complications including hemarthrosis, infection, fracture, wound impairment No visual and auditory impairment

Exclusion criteria:

The occurrence of any problem in the implementation of the plan Lack of patient willingness to continue cooperation Incidence of deep venous thrombosis

Age

From **50 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule Procedure : 12 pieces of paper showing A (representative of control group) and 12 pieces showing B (representative of intervention group) are mixed in a box. Every patient picks one of them and that paper will not be put back in the box. patients don't know what each letter (A or B) shows.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Iran University of Medical Sciences

Street address

Hemmat Highway, between sheykh fazlollah and Chamran Highways, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2018-02-25, 1396/12/06

Ethics committee reference number

IR.IUMS.REC 1396.9511340012

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

Exercise therapy after unilateral total knee arthroplasty

ICD-10 code

Z50.1

ICD-10 code description

Therapeutic and remedial exercises

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

Function

Timepoint

First and last sessions

Method of measurement

Timed up and go test, Stair climbing test, 6 minute walk test

Secondary outcomes**1****Description**

Pain

Timepoint

First and last sessions

Method of measurement

By using visual analogue scale

2**Description**

Range of motion

Timepoint

First and last sessions

Method of measurement

By using goniometer

3

Description

Quality of life

Timepoint

First and last sessions

Method of measurement

By using short form 36 questionnaire

4

Description

Hip and knee muscles strength

Timepoint

First and last sessions

Method of measurement

By using dynamometer

Intervention groups

1

Description

Control group: Patients in this group will take TENS and infrared radiation for 20 minutes and after that strengthening exercises of knee extensors and flexors and range of motion exercises.. The start of treatment sessions is two days after surgery and 3 times a week up to ten sessions.

Category

Rehabilitation

2

Description

Intervention group: control group interventions in addition to strengthening exercises of hip muscles

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Ali Amiri

Street address

Mansoori St, Sattar Khan St

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Phone

+98 21 6435 2575

Email

amiri.a@iums.ac.ir

2

Recruitment center

Name of recruitment center

Shafa Yahyaian Hospital

Full name of responsible person

Kourosh Mansory

Street address

Mujahedin-e-Islam St, Baharestan Square

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 3354 2001

Email

mansori.k@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Morteza Naserbakht

Street address

Hemmat highway, between Chamran and Sheikh Fadolallah highways, Iran University of Medical Sciences, headquarters, 5th floor

City

Tehran

Province

Tehran

Postal code

1545913187

Phone

+98 21 2222 8051

Email

naserbakht.m@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

Kazem Malakouti

Position

Vice chancellor for research

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

Street address

Hemat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۳۹۹۱۴۵۳۵

Phone

+98 21 8670 2503

Email

kmalakouti@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Akbari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation, Madadkaran Al., Shahnazari St., Madar Sq., Mirdamad Blvd.

City

Tehran

Province

Tehran

Postal code

۱۳۴۸۷ - ۱۵۴۵۹

Phone

+98 21 2222 8051

Fax

+98 21 2222 0946

Email

akbari.mo@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mojgan Moarref Khanli

Position

Master of Sciences student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

Madad Karan Al., Shahnazari St., Madar Sq., Mirdamad Blvd

City

Tehran

Province

Tehran

Postal code

1545913187

Phone

+98 21 2222 8052

Email

Mojgankhanli92@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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