

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of rehabilitation at home and outpatient physiotherapy after total knee Arthroplasty surgery on quality of life and knee function

Protocol summary

Study aim

Comparison of rehabilitation at home and outpatient physiotherapy after total knee replacement surgery

Design

This is a clinical trial study with two parallel groups, non-randomized, and open-label.

Settings and conduct

This study is conducted in Milad Hospital in Kashan. One group of knee joint replacement patients will be rehabilitated at home by a physiotherapist, and in the other group, rehabilitation measures will be performed in a physiotherapy center by the same physiotherapist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with end-stage osteoarthritis, patients with controlled blood pressure and diabetes, and patients whose BMI are 35 or below. Exclusion criteria: Neurological deficits, severe osteoarthritis of the opposite knee, and no willingness to participate in the study

Intervention groups

In both intervention groups, after discharge, patients will undergo two physiotherapy sessions per week for 10 weeks (20 sessions) by only one physiotherapist and based on the following physiotherapy protocols. The physiotherapy protocol specific to the intervention group will be based on TENS and HP modalities and high-power laser therapy on the knee and in the control group with modalities focused on strengthening the hip abductors and quadriceps muscle strengthening at home by a physiotherapist (physiotherapy focused on behaviors and movements will strengthen the quadriceps and hip abductors).

Main outcome variables

Knee function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221005056095N1**

Registration date: **2022-11-19, 1401/08/28**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-19, 1401/08/28**

Update count: **0**

Registration date

2022-11-19, 1401/08/28

Registrant information

Name

Abdollah Shakiba dastgerdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3244 2169

Email address

abdollahshakiba@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-22, 1401/07/30

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of rehabilitation at home and outpatient physiotherapy after total knee Arthroplasty surgery on quality of life and knee function

Public title

The effect of rehabilitation and physiotherapy after total knee Arthroplasty surgery on quality of life and knee function

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with end stage osteoarthritis Patients with controlled blood pressure and diabetes Patients whose BMI are 35 or below

Exclusion criteria:

Neurological deficits Severe osteoarthritis of the opposite knee Not willing to participate in the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

N/A

Randomization description

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 kashan University of Medical Sciences

Street address

15 khordad ave., kashan city

City

kashan

Province

Isfahan

Postal code

8715981151

Approval date

2022-09-05, 1401/06/14

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1401.103

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Knee function

Timepoint

before the operation and at intervals of one month, three months and 6 months after the operation

Method of measurement

Knee Society Score

2

Description

Quality of life

Timepoint

before the operation and at intervals of one month, three months and 6 months after the operation

Method of measurement

SF-36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients seeking discharge undergo two physiotherapy sessions per week for 10 weeks (20 sessions) by only one physiotherapist and based on physiotherapy protocols specific to the intervention group according to TENS and HP modalities and high power laser therapy on It will be the knee.

Category

Rehabilitation

2

Description

Intervention group: Patients after discharge will undergo two physiotherapy sessions per week for 10 weeks (20 sessions) by only one physiotherapist and with modalities focused on strengthening the hip abductors

and strengthening the quadriceps muscle at home by the physiotherapist. (Physiotherapy will focus on behaviors and movements to strengthen the quadriceps and hip abductors).

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad Hospital, Kashan

Full name of responsible person

Abdollah Shakiba Dastgerdi

Street address

Beheshti Hospital., Kashan City

City

Kashan

Province

Isfahan

Postal code

8715981151

Phone

+98 913 985 4783

Email

abdollahshakiba@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

Street address

Kashan University of Medical Sciences, Basic Sciences
Research Institute

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5558 9399

Email

hamidi_gh@kaums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

no

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

abdollah shakiba dastgerdi

Position

Orthopaedic resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Kashan., Beheshti hospital

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Phone

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Abdollah Shakiba Dastgerdi

Position

Orthopedic resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Abdollah Shakiba Dastgerdi

Position

Orthopedic resident

Latest degree

Medical doctor

Other areas of specialty/work

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not 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

All data can be shared after people have requested.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of results and data is allowed only in line with scientific and research goals in line with more comprehensive studies and investigations in more diverse research fields.

From where data/document is obtainable

Abdollah Shakiba Dastgerdi address

abdollahshakiba@yahoo.com

What processes are involved for a request to access data/document

After sending the email, the data will be sent within one month.

Comments