Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

The Effects of balance training on foot loading distribution after total knee arthroplasty

Protocol summary

Study aim

Determination of effects of balance training on foot loading distribution after total knee arthroplasty

Design

Two parallel group, Simple Randomized, Not blinded clinical trial, 30 patients.

Settings and conduct

Patients who meet the research entry criteria will refer to Razi Physiotherapy Clinic in Zarand. First, the patient's demographic and pain information will be completed to evaluate the subjective symptoms. Evaluation of foot pressure parameters before surgery, before and after intervention will be done by foot scanning device. In this study, the information collected from the foot pressure scanning device will be recorded. The baropodometric data collection tool will be a foot pressure scanner (Payatech model, PT-Scan4452F100). Then, the patients will be randomly assigned to two routine treatment groups (TENS, IR, exercise with emphasis on quadriceps muscle strengthening) and balance training group (TENS, IR, balance exercise).

Participants/Inclusion and exclusion criteria

Inclusion Criteria: A maximum time of 1 month after TKA, Unilateral arthroplasty, No physical therapy intervention/rehabilitation after hospital discharge for TKA, Age less than 80 years, No history of knee surgery within 6 months before the study. Exclusion Criteria: Patients who do not want to enter the study or cannot tolerate balance exercises will be excluded from the study.

Intervention groups

Intervention group: In this group, patients will receive balance exercises in addition to routine treatment. Balance exercises will include standing on one leg with eyes open and closed, anterior, lateral and posterior step-up exercises. Control group: In this group, patients will receive routine treatment including TENS, infrared radiation (IR) and stretching exercises.

Main outcome variables

The surface in contact with the ground in the foot, The oval area of the movement path of the center of body pressure, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180714040466N6**
Registration date: **2023-10-07, 1402/07/15**
Registration timing: **prospective**

Last update: **2023-10-07, 1402/07/15**
Update count: **0**

Registration date

2023-10-07, 1402/07/15

Registrant information

Name

Fateme Ghiasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 6708

Email address

f_ghiasi_p@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of balance training on foot loading distribution after total knee arthroplasty

Public title

The Effects of balance training on foot loading distribution after total knee arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Maximum 1 month after arthroplasty Patients with unilateral arthroplasty No history of bone diseases, Surgery and fractures around the knee No physical therapy intervention/rehabilitation after hospital discharge Ability walking more than 10 meters Years: Range: 50- 80

Exclusion criteria:

Musculoskeletal disease in the lower limbs Unwillingness to enter the study Balance disorder: dizziness Metabolic disorder Vascular disorder in lower limb

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the number of patients in each group, the particular sort of treatment (routine treatment groups or balance training group) is written on a piece of paper. Each paper is placed in a sealed envelope. One envelope will be chosen randomly by the therapist at the first session of the patient treatment and the patient's treatment technique is selected based on that. If any of the patients is omitted from the study, one envelope related to the excluded patient treatment group will be replaced and they will mixed again.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Dr. Hasabi Square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2023-08-20, 1402/05/29

Ethics committee reference number

IR.ZAUMS.REC.1402.195

Health conditions studied

1

Description of health condition studied

Total Knee Arthroplasty

ICD-10 code

Z96. 651

ICD-10 code description

Total Knee Arthroplasty

Primary outcomes

1

Description

The surface of foot contact with the ground

Timepoint

Before surgery, Baseline and at the end of the study

Method of measurement

Foot pressure scanning machine (Payatech model, PT-Scan4452F100)

2

Description

Pain Intensity

Timepoint

Before surgery, Baseline and at the end of the study

Method of measurement

Visual Analogue Scale (VAS)

3

Description

The ellipse area of the movement path of the Center of Body Pressure

Timepoint

Before surgery, Baseline and at the end of the study

Method of measurement

Foot pressure scanning machine (Payatech model, PT-

Scan4452F100)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, patients will receive balance exercises in addition to routine treatment. Patients will be trained with balance exercise rehabilitation program for 30 minutes, 6 days a week and for 24 sessions. Balance exercises will include standing on one leg with eyes open and closed, anterior, lateral and posterior step-up exercises in both legs of the patient.

Category

Rehabilitation

2

Description

Control group: In this group, routine treatment will be performed instead of balance exercises. First, patients undergo TENS (Transcutaneous Electrical Nerve Stimulation) electrotherapy (for 20 minutes) along with infrared radiation (IR) (for 10 minutes), and then, stretching exercises for the hamstring muscles and strengthening exercises for the quad muscles will be done for 30 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Physiotherapy Clinic

Full name of responsible person

Hosein Afzali

Street address

No.8 Alley, Bahonar St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr.Noormohammad Bakhshani

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Dr.Fateme Ghiasi

Position

Asistance professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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