

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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-

## 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.

##### City

Zarand

##### Province

Kerman

##### Postal code

7761868208

##### Phone

+98 34 3342 2531

##### Email

hoseinafzali1365@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Dr.Noormohammad Bakhshani

##### Street address

Dr.Hessabi Blvd

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9817643463

##### Phone

+98 54 3329 5796

##### Email

public @zamus.ac.ir

#### 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

##### Street address

Khatam al anbia Hosp, Jame jam Blvd

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9815733169

##### Phone

+98 54 3322 0501

##### Email

f\_ghiasi\_p@zamus.ac.ir

## Person responsible for scientific 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

**Street address**

Khatam al anbia Hosp, Jame jam Blvd Zahedan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9815733169

**Phone**

+98 54 3322 0501

**Email**

f\_ghiasi\_p@zamus.ac.ir

**Web page address**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Khatam al anbia Hosp, Jame jam Blvd Zahedan

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9815733169

**Phone**

+98 54 3322 0501

**Email**

f\_ghiasi\_p@zamus.ac.ir

## 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

## Person responsible for updating data

### Contact

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Dr.Fateme Ghiasi

**Position**

Asistance professor

**Latest degree**