

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of core stability training following hip arthroplasty on balance, physical function, and quality of life in patients with unilateral development dysplasia of the hip.

Protocol summary

Study aim

To determine the effect of core stability exercises on balance, functional ability, and quality of life after total hip arthroplasty in patients with unilateral developmental hip dislocation.

Design

This study is a randomized, double-blind, parallel-group controlled clinical trial conducted on 40 patients. Random allocation software was used for randomization.

Settings and conduct

The accessible population includes men and women who have undergone unilateral hip replacement surgery due to developmental hip dislocation at Irfan Niayesh Hospital in Tehran, performed by a hip subspecialist, and will be referred to the Shahid Beheshti University of Medical Sciences Rehabilitation Faculty.

Participants/Inclusion and exclusion criteria

unilateral total hip arthroplasty due to developmental hip dislocation, age range between 18 and 60 years, cementless total hip replacement using the subtrochanteric shortening osteotomy (digastric technique), absence of postoperative complications (infection, fracture, etc.), no history of other underlying conditions (discopathy, multiple sclerosis, etc.), and primary (first-time) total hip arthroplasty. total hip replacement due to other causes (advanced hip osteoarthritis, etc.), partial joint replacement, cemented or other surgical techniques, presence of surgical complications, presence of other underlying medical conditions, and revision surgery (second or subsequent joint replacement).

Intervention groups

In addition to the routine physiotherapy exercises following total hip replacement, the intervention group will also receive core stability exercises.

Main outcome variables

Quality of life; physical function; side effects; core

stability exercises; number of sit-to-stand tests; duration of standing on the operated leg; center of pressure (COP) velocity; center of pressure (COP) displacement.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260223068925N1**

Registration date: **2026-07-01, 1405/04/10**

Registration timing: **registered_while_recruiting**

Last update: **2026-07-01, 1405/04/10**

Update count: **0**

Registration date

2026-07-01, 1405/04/10

Registrant information

Name

fatemeh mallaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-06-27, 1405/04/06

Expected recruitment end date

2026-09-28, 1405/07/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of core stability training following hip arthroplasty on balance, physical function, and quality of life in patients with unilateral development dysplasia of the hip.

Public title

The effect of core stability training following hip arthroplasty on balance, physical function, and quality of life in patients with unilateral development dysplasia of the hip.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

unilateral total hip arthroplasty due to developmental hip dislocation. age range between 18 and 60 years. cementless total hip replacement using the subtrochanteric shortening osteotomy (digastric technique). absence of postoperative complications (such as infection, fracture, nerve injury, etc.). no history of other underlying conditions (e.g., discopathy, multiple sclerosis, advanced osteoarthritis of other joints, etc.). primary (first-time) total hip arthroplasty.

Exclusion criteria:

total hip replacement due to other causes (such as advanced hip osteoarthritis, avascular necrosis of the femoral head, etc.). partial joint replacement. cemented or other surgical techniques. presence of surgical complications. presence of other underlying medical conditions. revision surgery (second or subsequent joint replacement).

AgeFrom **18 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will be performed using Random Allocation Software. In the software settings, the number of groups will be set to two (Group A: intervention group; Group B: control group), with a 1:1 allocation ratio. A block size of 4 and a total sample size of 40 participants will be specified. The software will then generate a random allocation sequence. Whenever an eligible participant is enrolled in the study, they will be assigned to the next available allocation in the randomization sequence and allocated to either Group A or Group B.

The assigned group (A or B) will be written on a sealed envelope and provided for implementation of the intervention. Participants will remain unaware of their group assignment, whereas the treating physiotherapist will know the allocation in order to deliver the appropriate intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

The assessor will be blinded to the group allocation of the participants. The participants will also be unaware of whether they are assigned to the treatment group or the control group.

Placebo

Not used

Assignment

Parallel

Other design features

Few studies have examined the effects of core stability strengthening exercises after total hip arthroplasty, particularly in individuals with developmental hip dislocation. In this study, we aim to investigate the effects of core stability strengthening exercises on balance, functional ability, and quality of life in individuals with developmental hip dislocation following total hip replacement surgery.

Secondary Ids

empty

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

"Deputy of Research and Technology, Shahid Beheshti University of Medical Sciences (Research Ethics

Street address

"Unit 1 (West), No. 9, Tolou 3 St., Kouhak Blvd., Chitgar, Tehran, Iran"

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1485713616

Approval date

2025-08-17, 1404/05/26

Ethics committee reference number

IR.SBMU.RETECH.REC.1404.391

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

"Physiotherapy after Hip Joint Replacement in Individuals with Congenital Hip Dislocation"

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Quality of life

Timepoint

Individuals before starting core stability exercises (6 weeks after surgery), 6 weeks after starting core stability exercises (12 weeks after surgery), and 6 months after surgery.

Method of measurement

HOOS questionnaire

2

Description

physical function

Timepoint

Individuals before starting core stability exercises (6 weeks after surgery), 6 weeks after starting core stability exercises (12 weeks after surgery), and 6 months after surgery.

Method of measurement

TUG test

3

Description

core stability

Timepoint

Individuals before starting core stability exercises (6 weeks after surgery), 6 weeks after starting core stability exercises (12 weeks after surgery), and 6 months after surgery.

Method of measurement

Force plate

4

Description

number of sit-to-stand tests

Timepoint

Individuals before starting core stability exercises (6 weeks after surgery), 6 weeks after starting core stability exercises (12 weeks after surgery), and 6 months after surgery.

Method of measurement

sit-to-stand tests

5

Description

duration of standing on the operated leg

Timepoint

Individuals before starting core stability exercises (6 weeks after surgery), 6 weeks after starting core stability exercises (12 weeks after surgery), and 6 months after surgery.

Method of measurement

single leg stand test

6

Description

center of pressure (COP) velocity

Timepoint

Individuals before starting core stability exercises (6 weeks after surgery), 6 weeks after starting core stability exercises (12 weeks after surgery), and 6 months after surgery.

Method of measurement

Force plate

7

Description

center of pressure (COP) displacement

Timepoint

Individuals before starting core stability exercises (6 weeks after surgery), 6 weeks after starting core stability exercises (12 weeks after surgery), and 6 months after surgery.

Method of measurement

Force plate

8

Description

side effects

Timepoint

Individuals before starting core stability exercises (6 weeks after surgery), 6 weeks after starting core stability exercises (12 weeks after surgery), and 6 months after surgery.

Method of measurement

The participant will be interviewed using a structured questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient will attend the physiotherapy center 24 hours after surgery and will continue treatment for 6 weeks. During this period, the patient will attend the physiotherapy center three times per week. The treatment program will include 15 minutes of Transcutaneous Electrical Nerve Stimulation (TENS), 15 minutes of Interferential Therapy (IFT), hip strengthening exercises, range of motion exercises, gait training, and functional exercises (2 sets of 10 repetitions). If the patient develops lower-limb muscle spasms, dry needling or the Graston technique will be used as appropriate. Six weeks after surgery, a core stability exercise program will be initiated. The patient will attend the physiotherapy center twice weekly for 6 weeks. The core stability program will consist of 15 minutes of exercises designed to strengthen the abdominal, back, and gluteal muscles.

Category

Rehabilitation

2**Description**

Control group: The patient will attend the physiotherapy center 24 hours after surgery and will continue treatment for 6 weeks. During this period, the patient will attend the physiotherapy center three times per week. The treatment program will include 15 minutes of Transcutaneous Electrical Nerve Stimulation (TENS), 15 minutes of Interferential Therapy (IFT), hip strengthening exercises, range of motion exercises, gait training, and functional exercises (2 sets of 10 repetitions). If the patient experiences lower-limb muscle spasms, dry needling or the Graston technique will be applied as appropriate. After the initial 6-week period, the patient will attend the physiotherapy center twice weekly for an additional 6 weeks and will continue performing the same exercise program described above.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

PHysiotherapy Clinic of Erfan Neyesh Hospital

Full name of responsible person

Jamal Bakhshi

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Saeed Rahmani

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Web page address**Grant name**

none

Grant code / Reference number

ندارد

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

No

Title of funding source

none

Proportion provided by this source

1

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Mallaei

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Person responsible for updating data

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Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Fatemeh Mallaei

Position

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The results of the treatment will be published without
mentioning the names of the participants.

When the data will become available and for how long

It is expected that the data will be published
approximately 6 months after sampling and treatment.

To whom data/document is available

All individuals who need it.

Under which criteria data/document could be used

The data will be used to evaluate the effect of the
intervention performed.

From where data/document is obtainable

Project contact person / Project coordinator

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

Via phone call and email.

Comments

none