Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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
Country
Iran (Islamic Republic of)
Phone
+98 21 4608 9165
Email address
yaghobsalmani1357@gmail.com

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).
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target 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"
City
tehran
Province
Tehran
Postal code
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
Street address
No. 17, Bahar Street, Kabiri Tameh (Shahin) Street, West Hemmat Highway
City
Tehran
Province
Tehran
Postal code
147691949X
Phone
+98 21 4979 6260
Email
info@niayeshhospital.ir
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
Street address
Tehran, Imam Hossein Square, Damavand Street (Tehran Pars area), opposite , School of Rehabilitation Sciences, .
City
Tehran
Province
Tehran
Postal code
1616913111
Phone
+98 21 7754 2057
Fax
+98 21 7759 1807
Email
info@sbmu.ac.ir
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
Street address
"Unit 1 (West), No. 9, Tolou 3 St., Kouhak Blvd., Chitgar, Tehran, Iran"
City
Tehran
Province
Tehran
Postal code
1485713616
Phone
+98 21 4608 9765
Email
yaghobsalmani1357@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Mohsen Abedi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
Tehran, Imam Hossein Square, Damavand Street (Tehran Pars area), opposite , School of Rehabilitation Sciences, .

City
Tehran

Province
Tehran

Postal code
1616913111

Phone
00982177561721-242

Email
mohsenabedi110@sbmu.ac.ir

Web page address
https://isid.research.ac.ir/Mohsen_Abedi

Person responsible for updating data

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

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

City
Tehran

Province
Tehran

Postal code
1485713616

Phone
+98 21 4608 9165

Email
yaghobsalmani1357@gmail.com

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