# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**

**Recruitment complete**

**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