

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation and comparison of total hip arthroplasty results by cup placement in true or false acetabulum in patients with hip dysplasia with crow classification groups 3 and 4

Protocol summary

Study aim

Evaluation and comparison of total hip arthroplasty results by cup placement in true or false acetabulum in patients with hip dysplasia with crow classification groups 3 and 4

Design

Clinical trial without control group, phase 3 on 64 patients

Settings and conduct

This study is performed in Kashani Hospital in Isfahan. Selected patients undergo hip arthroplasty surgery to place the prosthesis in the true and false acetabulum. After the operation, the amount of pain and range of motion of the patients are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: developmental congenital hip dysplasia of crow 3 and 4; complete hip replacement for patients unilaterally or bilaterally; obtaining written consent. Exclusion criteria: defective information in the file; lack of access to the patient to complete the information; other skeletal abnormalities.

Intervention groups

Intervention group 1: patients in this group undergo hip arthroplasty by placing a prosthesis in the false acetabular cavity. One month and three months after surgery, patients' pain and range of motion of the hip joint will be measured and compared. Intervention group 2: patients in this group undergo hip arthroplasty by placing a prosthesis in the true acetabular cavity. One month and three months after surgery, patients' pain and range of motion of the hip joint will be measured and compared.

Main outcome variables

Pain and range of motion of the joint

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046523N5**

Registration date: **2020-10-20, 1399/07/29**

Registration timing: **prospective**

Last update: **2020-10-20, 1399/07/29**

Update count: **0**

Registration date

2020-10-20, 1399/07/29

Registrant information

Name

Aryan Rafiee Zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3837 1582

Email address

rafieezadeh.a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-04, 1399/08/14

Expected recruitment end date

2020-11-14, 1399/08/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of total hip arthroplasty results by cup placement in true or false acetabulum in patients with hip dysplasia with crow classification groups 3 and 4

Public title

Total hip arthroplasty by inserting a cup into a true or false acetabulum

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Developmental congenital hip dysplasia of crow 3 and 4
Complete hip replacement for patients unilaterally or bilaterally
Obtaining written consent

Exclusion criteria:

Defects in the information required by the file
Lack of access to the patient to complete the information
Another skeletal abnormality

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group. The researcher begins to read the numbers in a predetermined manner and the patients are divided.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan university of Medical sciences

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

۸۱۳۷۸۶۶۵۱۵

Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR.MUI.MED.REC.1397.072

Health conditions studied

1

Description of health condition studied

Developmental congenital hip dysplasia

ICD-10 code

Q87.5

ICD-10 code description

Other congenital malformation syndromes with other skeletal changes

Primary outcomes

1

Description

Pain

Timepoint

1 month and 3 months after intervention

Method of measurement

Visual Analogue Scale questionnaire

2

Description

Joint range of motion

Timepoint

1 month and 3 months after intervention

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: patients in this group undergo hip arthroplasty by placing a prosthesis in the false acetabular cavity. One month and three months after surgery, patients' pain and range of motion of the hip joint will be measured and compared.

Category

Treatment - Surgery

2

Description

Intervention group 2: patients in this group undergo hip arthroplasty by placing a prosthesis in the true acetabular cavity. One month and three months after surgery, patients' pain and range of motion of the hip joint will be measured and compared.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Mehdi Motiffard

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0042

Email

motiffard@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673118

Phone

+98 31 3668 0048

Email

haghjoo.sh@med.mui.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Motiffard

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3337 7986

Email

motiffard@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mehdi Motiffard

Position

Associate professor

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Person responsible for updating data

Contact

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Email

motiffard@med.mui.ac.ir

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

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments