Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of efficacy, safety and cost of using patient specific implants in distal femoral osteotomy in patients with cerebral palsy with Crouch gait compared to conventional method

Protocol summary

Study aim

The main objectives: Comparison of efficacy, safety and cost of using patient specific implants in distal femoral osteotomy in patients with cerebral palsy (Crouch gait) with conventional method in these patients Practical aim: Widespread use of patient specific implants in patients with cerebral palsy

Design

The clinical trial has a control group with parallel, one-blind, randomized, phase 1-2 groups on 20 patients with crouch gait. Random numbers used for randomization.

Settings and conduct

This study is a clinical trial study on cerebral palsy patients with crotchgate referred to Shariati Hospital. In order to design the implant, patients in the intervention group will undergo CT Scan scan. With the help of CT Scan images and computer software design, PSI and 3D design, surgical procedures will be performed. In control group, radiologic images will be taken to determine the location of osteotomy and planning for operation. Then, lateral operoch will be performed from the posterior muscle of the osteomy letral lastosis and angled blade plaque will be placed in place. After surgery, patients will be followed for 1 year. During this period, radiographic gait analysis, physical examinations, functional tests and postoperative complications will be evaluated. Cases such as duration of surgery and bleeding during surgery will also be evaluated in two groups. The final cost of surgery will be evaluated in two groups.

Participants/Inclusion and exclusion criteria

Documented diagnosis of CP spastic diplegic type Extreme curved walking Level I-III according to GMFCS Age ≤ 18 at the time of surgery

Intervention groups

40 CP patients with 20 are in group A, who treated by conventional method. 20 are in group B, who treated by PSI.

Main outcome variables

Knee pain Stiff knee Damage to nerves and vessels Motor function Quality of Life Not boiling bones Angularity of bone alignment Gate Analysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210712051854N5**
Registration date: **2022-12-23, 1401/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-23, 1401/10/02**
Update count: **0**

Registration date

2022-12-23, 1401/10/02

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy, safety and cost of using patient specific implants in distal femoral osteotomy in patients with cerebral palsy with Crouch gait compared to conventional method

Public title

Evaluation of patient specific implant outcomes in distal femoral osteotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Documented diagnosis of CP spastic diplegic type severe crouch gait (dorsey ankle flexion > 15 degrees, knee bending > 30 degrees, and pelvic extension <3 degrees in late stand-up in sagittal plate kinematics data) Level I-III according to GMFCS classification Minimum function of 3D gait analysis before and after surgery in the three months before surgery and at least 2 years after surgery Age ≤ 18 at the time of surgery

Exclusion criteria:

Patients with other motor disorders Any surgical prohibition (heart or respiratory problems) previous history of dorsal rhizotomy (Selective dorsal rhizotomy) botulinum toxin injection in the past 6 months or use of intraspinal baclofen pump

Age

From **4 years** old to **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block method was used for randomization. At first, blocks of 4 were defined using the randomization tool of the website https://www.sealedenvelope.com/simple-randomiser/v1/lists. Based on the placement order of groups A and B in each of these blocks, the order of the type of operation will be determined. Group A includes patients who will be treated with the old (conventional) method, and group B will be treated with the PSI method. The order of placement of patients in groups A and B in each of the blocks is determined based on the time of the patient's visit for surgery. For example, the first client is placed as person number one of block one in group A or B (determined by the software). The second client is placed as person number two of block one in group A or B (determined by the software). In this way, randomization will be done.

Blinding (investigator's opinion)

Single blinded

Blinding description

All patients will be given complete information about the surgical procedure of each of the two groups, case and control. Also, patients will be informed about the possibility of being placed in any of these two groups. After that, based on random numbers, patients are placed in one of the two groups A and B. Patients will not know which group they are in, and thus they will enter the study blind. In this way, the relevant intervention will be carried out in a one-sided blind way on the two study groups. The treating doctor, surgeon and other medical personnel will be informed about the type of treatment if needed. But all the people involved in the surgical process, hospitalization and subsequent follow-up of patients will be justified not to provide information about the type of operation to the patient. It should be noted that the surgical scar of both operations is the same and it is not possible to know the type of operation from the appearance of the operation site. If necessary, the doctor can determine the type of plaque used and therefore the patient's operation group based on the graphs obtained from the patients after the operation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Medical School-Tehran University of Medical Sciences

Street address

Islamic Revolution Street- University of Tehran

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Postal code

9561757393

Approval date

2022-08-11, 1401/05/20

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.316

Health conditions studied

1

Description of health condition studied

crouch gait in cerebral palsy

ICD-10 code

G80.8

ICD-10 code description

Other cerebral palsy

Primary outcomes

1

Description

Motor function collected by functional mobility scale questionnaire

Timepoint

6 months and 1 year after surgery

Method of measurement

The child's motor ability and gait in three specified distances (5,50,500 meters) will be measured using functional mobility scale questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group number 1: 20 cerebral palsy patients with crouch gait. Plaque design: First, 3D images are prepared with the help of ct scan, and with the help of it, special plaques for each patient are designed virtually. Then the plaques that are designed virtually are used by the casting expert team to make patient-specific plaques (PSI). In the next step, PSI is tested in terms of quality and resistance and other necessary criteria. Finally, PSI is sterilized and packaged and used for use in surgery. Surgical technique: Distal femur extension osteotomy is performed using a lateral approach to the end of the femur behind the vastus lateralis. Also, the patellar tendon is separated from the tibia and passes under the periosteal flap. Surgery in both groups will be performed by the same surgeons and surgical team. Patients will be examined in terms of clinical parameters (including pain level, joint range of motion, and gait status), radiography, and walking 1, 3, and then every 6 months after surgery until 12 months after surgery. In order to perform these examinations, patients will visit the clinic at specified times, and clinical and graphic examinations will be taken from the patients at the surgery site. The data obtained from these actions will be recorded in SPSS 25.0 software for statistical analysis.

Category

Treatment - Devices

2

Description

Intervention group number 2: 20 cerebral palsy patients with crouch gait. In this group, the common method of distal femur osteotomy and the use of angular blade plates will be used. These plates are designed with an angle of 90 degrees and after osteotomy, they fix the parts at the angle desired by the surgeon. 1, 3 and then every 6 months after surgery until 12 months after surgery will be checked. In order to perform these examinations, patients will visit the clinic at specified times, and clinical and graphic examinations will be taken from the patients at the surgery site. The data obtained from these actions will be recorded in SPSS 25.0 software for statistical analysis.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source
Tehran 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
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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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Information about the main outcome is shared

When the data will become available and for how long
After printing the results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Ensure participants' privacy Data will be provided to academic researchers

From where data/document is obtainable
e-mail

What processes are involved for a request to access

data/document

After submitting the request, the reviews will be carried out within a week and if possible, the data will be provided to them.

Comments