Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

The effects of epiphysiodesis on angular deformity using staple, screw or plate and screw in children

Protocol summary

Study aim
The aim of the current study is to compare outcomes of angular deformity correction procedures through three epiphysiodesis techniques including using staple, screw, screw and plaque in modifying angular deformities.

Design
Randomized clinical trial with three intervention parallel groups with outcome assessment

Settings and conduct
Background: Angular deformity treatment How: simple sampling Where: Clinics of Al-zahra and Kashani Method: Epiphysiodesis surgery with staple, screw and screw and plaque techniques

Participants/Inclusion and exclusion criteria
Inclusion criteria: Presence of non-physiological genu varum or valgum Presence of angular deformity diagnosed by an orthopedist Intermalleular diameter(IMD) of over 10 centimeters and intercondylar diameter (ICD) of over 6 centimeters Unmet criteria: Parents' dissatisfaction for study participation

Intervention groups
Patients with chief complaint of angular deformity underwent one of the following surgical procedures: Staple group:Following provisional pin embedding and detection of physis proximal and distal part, staple will be placed in the position of pins. Screw group:Following embedding provisional pins using C-arm, the physis position will be detected and epiphysiodesis will be performed using canulated screws. Screw and plaque group:Following provisional pin embedding, distal and proximal part of involved limb will be detected using C-arm and then the plaque will be embedded around the physis bilaterally and screws will be embedded in provisional pins situation bilaterally.

Main outcome variables
Average deviation of mechanical deformity prior to and after surgery, Deformity correction velocity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170912036152N3**
Registration date: **2018-12-12, 1397/09/21**
Registration timing: **retrospective**

Last update: **2018-12-12, 1397/09/21**
Update count: **0**

Registration date
2018-12-12, 1397/09/21

Registrant information

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Ghasem Mohammadsharifi
Name of organization / entity
Isfahan university of medical sciences
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Recruitment status
Recruitment complete

Funding source
isfahan university of medical sciences

Expected recruitment start date
2015-01-01, 1393/10/11

Expected recruitment end date
2017-01-01, 1395/10/12

Actual recruitment start date
2015-01-01, 1393/10/11

Actual recruitment end date
2017-03-21, 1396/01/01

Trial completion date
2017-03-21, 1396/01/01

Scientific title
The effects of epiphysiodesis on angular deformity using staple, screw or plate and screw in children

Public title
pain management in total knee arthroplasty (TKA)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The presence of non-physiological genovugum or genovalogom with its numerical value Having a kind of angular deformity detected by an orthopedic specialist. Intermediate distance (IMD) above 10 cm, or Intercondillier spacing (ICD) greater than 6 centimeters Parental consent to participate in this study If the mechanical axis of the lower limb is not placed on the knee (outside or inside the knee)
Exclusion criteria:
Uncontrolled metabolic disease There is less than 12 months to stop the growth of the bone
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Actual sample size reached: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
All patients were provided self-specific number using random allocation software and then were divided in three groups based on their numbers of 3k, 3k+1 and 3k+2
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
Isfahan Medical School Ethic Committee
Street address
Hezar Jarib
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Isfahan
Province
Isfehan
Postal code
8196736573
Approval date
2017-05-31, 1396/03/10
Ethics committee reference number
IR.MUI.REC.1396.3.832

Health conditions studied

1

Description of health condition studied
Angular deformity
ICD-10 code
Q74.1
ICD-10 code description
Congenital malformation of knee

Primary outcomes

1

Description
Average deviation of mechanical deformity
Timepoint
Prior to the surgery, immediately after surgery and then every three months until a year
Method of measurement
Using Anterior-Posterior radiography

Secondary outcomes

1

Description
Deformity correction velocity
Timepoint
Every three months until a year
Method of measurement
Measurement and comparison of deformity angle using anterior-posterior radiography

Intervention groups

1

Description
Intervention group: Staple group: After patients' positioning in supine position, following provisional pin embedding and detection of physis proximal and distal part, the skin would be incised and staple will be placed in the position of pins(Osveh; Iran).
Category
Treatment - Surgery

2

Description

Intervention group: Screw group: After patients' positioning in supine position, following embedding provisional pins using C-arm, the physis position will be detected and epiphysiodesis will be performed using canulated screws(Osveh; Iran).

Category

Treatment - Surgery

3

Description

Intervention group: Screw and plaque group:After patients' positioning in supine position, following provisional pin embedding, distal and proximal part of involved limb will be detected using C-arm and then the skin will be incised and plaque will be embedded around the physis bilaterally and screws will be embedded in provisional pins situation bilaterally(Osveh; Iran).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Kashani Hospital
Full name of responsible person
Dr Mohammad Ali Tahririan
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2

Recruitment center

Name of recruitment center
Al-zahra Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

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
Isfahan University of Medical Sciences
Full name of responsible person
Ghasem Mohammadsharifi
Position
Orthopaedic Resident
Latest degree
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Latest degree

Subspecialist

Other areas of specialty/work

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Web page address

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

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

Data are type of surgical procedure, deformity correction rate and required duration for deformity correction

When the data will become available and for how long

Since project cessation and its submission, the end of 2019

To whom data/document is available

Researchers who want to compare their projects about angular deformity correction with our findings

Under which criteria data/document could be used

For comparison of different surgical procedures with findings of our study

From where data/document is obtainable

Corresponding of this stud, Dr. Sharifi and Dr. Tahririan should be referred.

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

The correspondent professor, Dr. Tahririan should be contacted. Then he can provide an SPSS file. This request should be done thorough an Email and proposal and/or an official request from the university.

Comments