Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of caudal block under ultrasound guide in controlling pain in children before and after knee osteotomy

Protocol summary

Study aim
Evaluation of the effect of caudal block under ultrasound guide in controlling pain in children before and after knee osteotomy

Design
A randomized controlled clinical trial with parallel, double-blind, randomized groups.

Settings and conduct
50 patients were enrolled in the study and randomly divided into two groups of 25 patients. In all patients, the amount of pain is measured before the operation according to VAS criteria. The first intervention group, after induction and intubation under the caudal block, was placed in the lateral position with a dose of 0.5 cup / kg of 0.2% rupivacaine. In the second intervention group, the lateral block is injected in the lateral position after surgery and before extubation with a dose of 0.5 cp / kg of 0.2% rupivacaine. They are then reversed and extubated with neostigmine 0.04 mg / kg and atropine 0.02 mg / kg.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children undergoing knee osteotomy surgery Exclusion criteria: Systemic infection, Infection of the needle insertion site, Coagulation disorder

Intervention groups
Intervention Group 1: After induction and intubation, they were placed in the lateral position under the caudal block at a dose of 0.5 cc / kg of 0.2% rupivacaine. Intervention Group 2: Catral block under lateral position after injection and before extubation with 0.5 cc / kg dose of 0.2% rupivacaine is injected. They are then reversed and extubated with neostigmine 0.04 mg / kg and atropine 0.02 mg/kg.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180723040570N6**
Registration date: **2022-01-14, 1400/10/24**
Registration timing: **prospective**

Last update: **2022-01-14, 1400/10/24**
Update count: **0**

Registration date
2022-01-14, 1400/10/24

Registrant information

Name
Nasim Nikoubakht

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8862 9854

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nikoobakht.n@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-20, 1400/12/01

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of caudal block under ultrasound guide in controlling pain in children before and after knee osteotomy

Public title
Effect of caudal block under ultrasound guide in controlling pain of knee osteotomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children two to six years old are candidates for knee osteotomy surgery Consent from parents
Exclusion criteria:
Coagulation disorder Infection of the needle insertion site Systemic infection
Age
From **2 years** old to **6 years** old
Gender
Both

Phase
2
Groups that have been masked

- Care provider
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block, we divide 4 people into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2020-09-06, 1399/06/16
Ethics committee reference number
IR.IUMS.FMD.REC.1399.383

Health conditions studied

1

Description of health condition studied
Osteotomy
ICD-10 code
M92.8
ICD-10 code description
Other specified juvenile osteochondrosis

Primary outcomes

1

Description
Pain
Timepoint
Before and after surgery
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After induction and intubation, they were placed in the lateral position under the caudal block at a dose of 0.5 cp / kg of 0.2% rupivacaine.
Category
Treatment - Devices

2

Description
Intervention group: Catral block under lateral position is injected after surgery and before extubation with 0.5 cc /

kg dose of 0.2% rupivacaine.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasul-e Akram hospital

Full name of responsible person
Fatemeh Ahmadi

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Nyayesh ST.Sattarkhan ST.Rasul-e Akram Hospital

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Sponsors / Funding sources

1

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Fatemeh Ahmadi

Position
Rezident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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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
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 potential data is shared after unidentifiable people.

When the data will become available and for how long
Start of access period 6 months after printing results

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

Under which criteria data/document could be used
There are no special conditions.

From where data/document is obtainable
Fatemeh Ahmadi

What processes are involved for a request to access data/document
En After reviewing the applicant's request, it will be sent to him.

Comments