

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% ropivacaine. 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% ropivacaine. 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% ropivacaine.
Intervention Group 2: Catral block under lateral position after injection and before extubation with 0.5 cc / kg dose of 0.2% ropivacaine 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)

Phone

+98 21 8862 9854

Email address

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% ropivacaine.

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

Street address

Nyayesh ST.Sattarkhan ST.Rasul-e Akram Hospital

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 4001

Fax

+98 21 6650 6864

Email

Bahar.ahmadi69@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motevalian

Street address

Iran University of Medical Sciences, Next to Milad
Tower, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 6651 4001

Fax

+98 21 6650 6864

Email

nnikobakht@yahoo.com

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

Street address

Nyayesh ST.Sattarkhan ST. Rasul-e Akram Hospital

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 4001

Email

Bahar.ahmadi69@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Ahmadi hafshejani

Position

Rezident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Nyayesh ST.Sattarkhan ST.Rasul-e Akram Hospital

City

Tehran

Province

Tehran

Postal code

1969714713

Phone

+98 21 6651 4001

Fax

+98 21 6650 6864

Email

Person responsible for updating data

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

Street address

Shahid Valinejad Alley, Above Vanak Square, Vali Asr St

City

Tehran

Province

Tehran

Postal code

1969714713

Phone

+98 21 81161

Email

jhoseini2003@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

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