Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparing caudal block and penile block using rectal acetaminophen in postoperative analgesia of hypospadiasis repair

Protocol summary

Study aim
Comparing caudal block and penile block using rectal acetaminophen in postoperative analgesia of hypospadiasis repair in children aged 6 months to 5 years

Design
A clinical trial with parallel, double-blind, randomized, permutation-block, phase 3 was performed on 50 patients in both equal groups.

Settings and conduct
Phase 3 clinical trial with two parallel groups was performed on 50 patients referred to Shahid Motahari Hospital in Urmia. Patients were enrolled in two equal groups (caudal group = 25 people and penile group = 25 people). In this study, patients and clinical assessor as well as statistical analyzers were unaware of group assignment. Randoization method was permuted-block.

Participants/Inclusion and exclusion criteria
Inclusion criteria: American Society of Anesthesiologists (ASA) ≤II,Absence of spinal deformity, Age between 6 months to 5 years, Children need hypospadias repair
Exclusion criteria: Coagulation problems, Severe infections such as septicemia, meningitis, Brain tumors with increased intracranial pressure, Real sensitivity to local anesthetics, Chemotherapy, Unmodified hypovolemia,

Intervention groups
First intervention group: Caudal block Second intervention group: Penile block using rectal acetaminophen

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170516033992N2**
Registration date: **2020-10-06, 1399/07/15**
Registration timing: **retrospective**

Last update: **2020-10-06, 1399/07/15**
Update count: **0**

Registration date
2020-10-06, 1399/07/15

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3222 2010
Email address
karami.t@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-23, 1398/12/04

Expected recruitment end date
2020-07-04, 1399/04/14

Actual recruitment start date
2020-02-26, 1398/12/07

Actual recruitment end date
2020-07-19, 1399/04/29

Trial completion date
2020-07-19, 1399/04/29

Scientific title
Comparing caudal block and penile block using rectal acetaminophen in postoperative analgesia of hypospadiasis repair

Public title
The effect of caudal block and penile block in postoperative analgesia of hypospadiasis repair

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 6 months to 5 years Absence of spinal deformity ASA class ≤II Children need hypospadias repair
Exclusion criteria:
Coagulation problems Severe infections such as septicemia, meningitis Brain tumors with increased intracranial pressure Real sensitivity to local anesthetics Chemotherapy Unmodified hypovolemia
Age
From **6 months** old to **5 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will conduct based on permuted block randomization method. Within each block, subjects will be randomly and equally assigned to caudal group (n=25) or penile group (n=25). Random assignment will be done using a random number table. That is, with the help of the Rand () command in Excel, we create random numbers, then we specify the numbers less than 0.5 with P, which means the penile group, and the numbers more than 0.5 with Q, which means the caudal group. The created sequence is random and the blocks continue until the number of samples is completed
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients were unaware of their placement in the intervention groups and the clinical assessor was unaware of the placement of patients in the study groups and the statistical analyzer received the data in code, not the actual grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
Jahad Sq., Resalat St., Urmia University of Medical Sciences
City
Urmia
Province
West Azarbaijan
Postal code
5715833631
Approval date
2020-02-18, 1398/11/29
Ethics committee reference number
IR.UMSU.REC.1398.508

Health conditions studied

1

Description of health condition studied
Hypospadias
ICD-10 code
Q54
ICD-10 code description
Hypospadias

Primary outcomes

1

Description
Pain
Timepoint
In recovery, 6, 12 and 24 hours after surgery
Method of measurement
The face, legs, activity, cry, consolability (FLACC) scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: This group of patients underwent caudal block in the lateral decubitus position with needle 22 Guage from the sacral space of hiatus with 1 ml of bupivacaine 0.25% (British-Swedish company of AstraZeneca) and epinephrine with a concentration of 1/200000 (5 µg / kg). In fact, this intervention is a kind of regional anesthesia procedure through the caudal region. The group was under general anesthesia, but caudal was also performed for postoperative analgesia.
Category
Treatment - Other

2

Description
Intervention group 2: In the penile block group, after general anesthesia with the condition of the caudal block group in the supine position under the penile block with a needle 22 Guage and bupivacaine 0.25%, 0.1 ml / kg from two sites in the retro-pubic space under the fascia of the book was performed. Acetaminophen suppository was administered at a dose of 40 mg / kg before surgery.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Urmia Shahid Motahari University Hospital

Full name of responsible person
Tohid Karami

Street address
Jahad Sq., Resalat St., Urmia University of Medical Sciences

City
Urmia

Province
West Azarbaijan

Postal code
5715833631

Phone
+98 44 3348 9752

Fax
+98 44 3345 7287

Email
karami.tohid@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Tohid Karami

Street address
Jahad Sq., Resalat St., Urmia University of Medical Sciences

City
Urmia

Province
West Azarbaijan

Postal code
5715833631

Phone
+98 44 3348 9752

Email
karami.tohid@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Tohid Karami

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Jahad Sq., Resalat st., Urmia University of Medical Sciences

City
Urmia

Province
West Azarbaijan

Postal code
5715833631

Phone
+98 44 3193 7000

Fax
+98 44 3345 7287

Email
karami.tohid@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Tohid Karami

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West Azarbaijan

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5715833631

Phone
+98 44 3193 7000

Fax
+98 44 3345 7287

Email
karami.tohid@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Tohid Karami

Position
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Fax
+98 44 3345 7287

Email
karami.tohid@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
Information can be provided without patients' names

When the data will become available and for how long
1 سال پس از اتمام مطالعه

To whom data/document is available
Faculty researchers

Under which criteria data/document could be used
Sending email to DR. Tohid Karami

From where data/document is obtainable
Sending email to DR. Tohid Karami

What processes are involved for a request to access data/document
Just sending email to DR. Tohid Karami

Comments