

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Comparison of the Effects of Suppository Acetaminophen, Local Marcaine Infiltration and Caudal Block with Marcaine on Postoperative Pain in Pediatric Inguinal Herniorrhaphy

Protocol summary

Summary

Objective: Control of postoperative pain is very important especially in pediatric patients and poor pain control leads to several complications such as different organs dysfunction and behavioral problems. We compared the analgesic effect of suppository acetaminophen, infiltration of marcaine in incisional site and caudal block with marcaine on postoperative pain in inguinal herniorrhaphy in children. Methods: In this randomized, controlled clinical trial study, 90 children between the ages of 3 month to 7 years, ASA I-II, scheduled for elective unilateral inguinal herniorrhaphy were assigned to three equal groups. For postoperative analgesia, patients in the first group received suppository acetaminophen 20mg/kg, in the second group 2mg/kg marcaine 0.5% was infiltrated in the incisional site and in the third group caudal block was performed with 0.75 ml/kg marcaine. Premedication, induction and maintenance of anesthesia were the same in these three groups. For comparison of the effect of these three methods, initially FLACC(F=Face, L=Leg, A=Activity, C=Crying, C=Consolability) pain scale was evaluated 30 minutes after operation in the recovery room. Then FLACC pain scale was measured every one hour during the next 6 hours of postoperative period. The data were transferred to the SPSS-10 software and analyzed statistically with chi-square and analysis of variance test. P-Value less than 0.05 was considered meaningful. Primary outcome measure :analgesia Primary outcome time point:30minutes after operation in the recovery room and the next six hours with one hour interval Primary outcome method of measurement:FLACC scale

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110027695N1**

Registration date: **2011-10-18, 1390/07/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-10-18, 1390/07/26

Registrant information

Name

Seyedeh Masoumeh Hosseini Valami

Name of organization / entity

Qazvin University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice- chancellor for research ,Qazvin, university of medical sciences

Expected recruitment start date

2007-12-22, 1386/10/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the Effects of Suppository Acetaminophen, Local Marcaine Infiltration and Caudal Block with Marcaine on Postoperative Pain in Pediatric Inguinal Herniorrhaphy

Public title

The Comparison of the Effects of Suppository Acetaminophen, Local Marcaine Infiltration and Caudal Block with Marcaine on Postoperative Pain in Pediatric Inguinal Herniorrhaphy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : the ages of 3 month to 7 years, ASA I-II, scheduled for elective unilateral inguinal heniorrhaphy were assigned to three equal groups exclusion criteria :Patients with positive history of consumption of sedative;anxiolytic; opioids; corticostetroids and anticonvulsive drugs had been excluded from the study.

Age

To **7 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethics committee of Qazvin university of medical sciense

Street address

Shahid Bamonar Blv, Qazvin City

City

Qazvin

Postal code

Approval date

2007-03-11, 1385/12/20

Ethics committee reference number

28/20/596

Health conditions studied

1

Description of health condition studied

Hernia

ICD-10 code

K40.3

ICD-10 code description

Unilateral or unspecified inguinal hernia, with obstruction, without gangrene

Primary outcomes

1

Description

analgesia

Timepoint

30 minutes after operation in the recovery room and the next six hours with one hour interval

Method of measurement

scale FLACC

Secondary outcomes

empty

Intervention groups

1

Description

Intervention1: Suppository acetaminophen 20mg/kg

Category

Treatment - Drugs

2

Description

Intervention2: 2mg/kg marcaine 0.5% was infiltrated in the incisional site

Category

Treatment - Drugs

3

Description

Intervention3: Caudal block was performed with 0.75 ml/kg marcaine(0.25%)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods Hospital

Full name of responsible person

Dr Seyedeh Masomeh Hosseini Valami

Street address

Qods square, Qods Hospital , Qazvin City

City

Qazvin

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

vice-chancellor for research ,Qazvin university of medical sciences

Full name of responsible person

Dr Saeed Asefzadeh

Street address

Shahid Bahonar, Qazvin City

City

Qazvin

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

vice-chancellor for research ,Qazvin university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Qazvin, University of Medical Sciences

Full name of responsible person

Dr Seyedeh Masomeh Hosseini Valami

Position

Assistant Professor/Anesthesia

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty