

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The Comparison of Bupivacaine, Bupivacaine-dexmedetomidine and Bupivacaine - fentanyl by caudal technique for postoperative analgesia in children 1-5 years old in pediatric hospital.

Protocol summary

Summary

The aim of this study is to compare the effects of bupivacaine, bupivacaine-dexmedetomidine and bupivacaine-fentanyl with caudal technique for postoperative analgesia. This double blinded clinical trial will be applied to 60 patients. Inclusion criteria: Children 1-5 years old, elective inguinal hernia operations. Exclusion criteria: cardiac-pulmonary congenital anomalies, history of drug allergy to the drugs used, contraindications to caudal block, cases with ASA class > I. The demographic and hemodynamic variables will be collected before and during and after anesthesia. induction and maintenance of anesthesia will be with sevoflurane in N2O and O2. before intubation of trachea atracurium 0.5 mg/kg will be applied. afterwards a caudal block will be done by an anesthesiologist. the first group will receive 1 ml/kg bupivacaine 0.25%, which will be prepared by adding equal volume of distilled water to 0.5% bupivacaine. the second group (bupivacaine-dexmedetomidine) will receive 1 ml/kg bupivacaine 0.25% with 2 µg/kg dexmedetomidine. The third group (bupivacaine-fentanyl) will receive 1 ml/kg bupivacaine 0.25% with 2 µg/kg fentanyl. intravenous fluid 6 ml/kg/hr during the operation and 4 ml/kg/hr after operation. Pain, sedation and motor block scores will be collected at 30 and 60 minutes of recovery and at 1, 2, 4, 6, 12 and 24 hours after operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110318091N6**
Registration date: **2016-01-23, 1394/11/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-23, 1394/11/03

Registrant information

Name

Fekrat Fereydoon

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2015-12-21, 1394/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of Bupivacaine, Bupivacaine-dexmedetomidine and Bupivacaine - fentanyl by caudal technique for postoperative analgesia in children 1-5 years old in pediatric hospital.

Public title

Comparing the effect of three local anesthesia drug

regimes Bupivacaine, Bupivacaine-dexmedetomidine and Bupivacaine - fentanyl through an injection through the tail portion of the spinal column for providing postoperative analgesia in children one to five years old in a children's hospital.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children aged 1-5 years old; elective inguinal hernia operations. Exclusion criteria: cardiac-pulmonary congenital anomalies; history of drug allergy to the drugs used; contraindications to caudal block; cases with ASA class > I.

Age

From **1 year** old to **5 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy for Research, and Medical Ethics Committee of Hormozgan University of Medical Sciences

Street address

Joomhoori Islami Blv., Shahid Mohammadi Hospital,

City

Bandar Abbas

Postal code

7919915519

Approval date

2014-10-30, 1393/08/08

Ethics committee reference number

4-HEC-93-7-8

Health conditions studied

1

Description of health condition studied

Postoperative pain in children

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

Pain

Timepoint

at time points of 30 and 60 minutes after operation in recovery room and at 1st, 2nd, 4th, 6th, 12th and 24th hours after operation in the surgery unit.

Method of measurement

Face Pain Scale Revise (FPS-R)

Secondary outcomes

1

Description

Heart rate

Timepoint

Every 10 minute after caudal block till and every 5 minute

Method of measurement

Anesthesia electrocardiographic monitoring equipment

2

Description

Arterial oxygen saturation

Timepoint

10 minutes after caudal block till the start of operation and with 5 minute intervals till the end of operation

Method of measurement

Pulse oximeter device

3

Description

Arterial blood pressure

Timepoint

Every 10 minute after caudal block till and every 5 minute

Method of measurement

No ninvasive blood pressure monitoring device

4

Description

Sedation

Timepoint

At 30 and 60 minutes after operation in the recovery room and at the 1st, 2nd, 4th, 6th, 12th and 24th hours time points

Method of measurement

Intervention groups

1

Description

First group (bupivacaine) which included 1 milliliter/kilogram from a solution of 0.25% bupivacaine which was prepared by adding distilled water to 0.5% bupivacaine with equal volumes.

Category

Prevention

2

Description

Second group (bupivacaine-dexmedetomidine) which included 1 milliliter/kilogram from a solution of 0.25% bupivacaine which was prepared by adding distilled water to 0.5% bupivacaine and 2 microgram/kilogram dexmedetomidine with equal volumes.

Category

Prevention

3

Description

Third group (bupivacaine-fentanyl) which included 1 milliliter/kilogram from a solution of 0.25% bupivacaine which was prepared by adding distilled water to 0.5% bupivacaine and 2 microgram/kilogram fentanyl with equal volumes.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Hospital

Full name of responsible person

Hashem Jarineshin

Street address

Goolshahr Shomali - Daroopakhsh Blvd.

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Abdulazim Nejatizadeh

Street address

Joomhoori Islami Blv., Deputy of Research Center,
Shahid Mohammadi Hospital

City

Bandar Abbas

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hormozgan 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

Hormozgan University of Medical Sciences

Full name of responsible person

Hashem Jarineshin

Position

Assistant Professor of Anesthesiology and Intensive care, Fellowship of Cardiac Surgery Anesthesia

Other areas of specialty/work

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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