Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 post operative 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

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Fekrat Fereydoon
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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 electrocardioraphic 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

Michigan University Sedation Scale

Intervention groups

1

Description
First group (bupivacaine) which included 1 milliliter/kilogram from a solution of 0.25% buupivacaine 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