

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect of neostigmine and fentanyl when added to bupivacaine in caudal analgesia in inguinal herniorrhaphy for children aged between 1 to 6 years double-blind clinical study

Protocol summary

Summary

The aim of the present double-blind randomized clinical trial is to compare efficacy and adverse effects of neostigmine against fentanyl when used as adjuvant to bupivacaine in caudal anesthesia. A total of 140 children, aged 1-6 year and ASA physical status I, who are scheduled to elective herniorrhaphy, are enrolled. Exclusion criteria are sacral area infection, history of allergic reactions to local anesthetics, bleeding tendency, neurological or spinal disease and lack of parent consent. Patients are assigned, using permuted block randomization method, into four groups of 35. Children in the first group receive a caudal injection of 0.5 ml/kg bupivacaine 0.25% plus fentanyl 1 μ /kg. The second group receive 0.5 ml/kg bupivacaine 0.25% plus neostigmine 1 μ /kg. Patients in the third group receive 0.5 ml/kg bupivacaine 0.25% plus combination of fentanyl 1 μ /kg and neostigmine 1 μ /kg, and those in the fourth group only receive 0.5 ml/kg bupivacaine 0.25% concentration. Heart rate (HR), and blood pressure (BP) are recorded every 15 minutes. To assess pain intensity, we use the standard pain questionnaire (Wong-Baker Scale). Hemodynamic changes and drug side effects (nausea and vomiting) are recorded in recovery room and surgery ward in different time points. Also, the time to first analgesic request and the dosage of analgesic agent is recorded. Patients and the researcher who assessed and recorded the data were blinded to group allocation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051126866N3**

Registration date: **2017-06-11, 1396/03/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Amir Shafa

Name of organization / entity

Isfahan University of Medical Sciences, Imam hossein Hospital

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 2655

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Isfahan University Of Medical Sciences

Expected recruitment start date

2017-05-31, 1396/03/10

Expected recruitment end date

2018-05-31, 1397/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of neostigmine and fentanyl when added to bupivacaine in caudal analgesia in inguinal herniorrhaphy for children aged between 1 to 6 years double-blind clinical study

Public title

Effect of adding neostigmine and fentanyl to bupivacaine in caudal analgesia

Purpose

Treatment

Inclusion/Exclusion criteria

A total of 140 children, aged 1-6 year and ASA physical status I, who were scheduled to elective herniorrhaphy, were enrolled. Exclusion criteria were sacral area infection, history of allergic reactions to local anesthetics, bleeding tendency, neurological or spinal disease and lack of parent consent.

Age

From **1 year** old to **6 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

using permuted block randomization method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University Of Medical Sciences

Street address

Isfahan-Isfahan University Of Medical Sciences

City

Isfahan

Postal code

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

394540

Health conditions studied

1

Description of health condition studied

local anesthetics

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

pain

Timepoint

every 15 minutes after intervention

Method of measurement

Wong Baker Scale

Secondary outcomes

1

Description

Blood Pressure

Timepoint

Every 15 minutes after intervention

Method of measurement

mm Hg

Intervention groups

1

Description

Patients were assigned, using permuted block randomization method, into four groups of 35. Children in the first group received a caudal injection of 0.5 ml/kg bupivacaine 0.25% plus fentanyl 1µ/kg. The second group received 0.5 ml/kg bupivacaine 0.25% plus neostigmine 1µ/kg. Patients in the third group received 0.5 ml/kg bupivacaine 0.25% plus combination of fentanyl 1µ/kg and neostigmine 1µ/kg, and those in the fourth group only received 0.5 ml/kg bupivacaine 0.25% concentration.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Amir Shafa

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Mehdi Nematbakhsh MD

Street address

Isfahan-Isfahan University Of Medical Sciences

City

Isfahan

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 of Isfahan 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

Isfahan University Of Medical Science

Full name of responsible person

Amir Shafa

Position

Anesthesiologist, Assistant Professor

Other areas of specialty/work

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Position

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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