Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 1µ/kg. The second group receive 0.5 ml/kg bupivacaine 0.25% plus neostigmine 1µ/kg. Patients in the third group receive 0.5 ml/kg bupivacaine 0.25% plus combination of fentanyl 1µ/kg and neostigmine 1µ/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)

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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 Universiy Of Medical Sciences
Street address
Isfahan-Isfahan Universiy 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 aneasthetics
ICD-10 code
Y48.3
ICD-10 code description
Local anaesthetics

Primary outcomes

1

Description
pain
Timepoint
evry 15 minutes after intervention
Method of measurement
Wong Baker Scale

Secondary outcomes

1

Description
Blood Pressure
Timepoint
Every 15 minutes aftere 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 Sceince
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Amir Shafa
Position
Anesthesiologist, Assistant Professor
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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