

# 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 1 $\mu$ /kg. The second group receive 0.5 ml/kg bupivacaine 0.25% plus neostigmine 1 $\mu$ /kg. Patients in the third group receive 0.5 ml/kg bupivacaine 0.25% plus combination of fentanyl 1 $\mu$ /kg and neostigmine 1 $\mu$ /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

###### Email address

amir\_shafa@med.mui.ac.ir

##### 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 anaesthetics

#### 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 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 1 $\mu$ /kg. The second group received 0.5 ml/kg bupivacaine 0.25% plus neostigmine 1 $\mu$ /kg. Patients in the third group received 0.5 ml/kg bupivacaine 0.25% plus combination of fentanyl 1 $\mu$ /kg and neostigmine 1 $\mu$ /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

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## Person responsible for scientific inquiries

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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*