

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparison of effect of caudal block and wound infiltration with bupivacaine in acute postoperative pain control in children after elective lower abdominal surgery with general anesthesia

Protocol summary

Summary

This study compares wound infiltration with bupivacaine and caudal block in acute postoperative pain reduction in children . the purpose of this study is if wound infiltration as effective as caudal approach in reducing acute postoperative pain, it can be a safe , fast alternative technique for caudal block . this is a double blinded , single centered , randomised clinical trial controlled with standard group without placebo , and , patients and their parents are not aware of groups. papulation of study consist of fifty-five , 2-8 years old , ASA class I-II patients undergoing elective lower abdominal surgery . exclusive criteria included urgent surgery , sensitivity to local anesthetics , G6PD deficiency , coagulative disorder , localized infection , parents refusal and pre-existing neurologic disorder. after induction of general anesthesia , at the end of surgery , patients randomly receive one of caudal block or wound infiltration interventions , and then informations about postoperative pain intensity, parental satisfaction, duration of analgesia provided by each technique , and the time of first urination and bowel activity record 1, 6 , 12, 24 hour after operation and analyse statistically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307308391N2**
Registration date: **2013-08-11, 1392/05/20**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-08-11, 1392/05/20

Registrant information

Name

Mehrsima Abdollahzadeh

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

guilan university of medical sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-08-22, 1393/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of effect of caudal block and wound infiltration with bupivacaine in acute postoperative pain control in children after elective lower abdominal surgery with general anesthesia

Public title

Acute abdominal Postoperative Pain Control in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : 2-8 years old patient with ASA class I-II

under elective lower abdominal surgery (aug 2013 - aug 2014) Exclusion criteria : ASA class III- IV , urgent surgery , sensitivity to local anesthetics , G6PD deficiency , coagulation disorder , localized infection , parents refusal, pre-existing neurologic disorder

Age

From **2 years** old to **8 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **55**

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

Guilan University of Medical Sciences

Street address

Azodi street

City

Rasht

Postal code

4193833697

Approval date

2013-07-29, 1392/05/07

Ethics committee reference number

1920141905

Health conditions studied

1

Description of health condition studied

acute postoperative pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

acute postoperative pain

Timepoint

1-6-12-24 hour after procedure

Method of measurement

modified objective pediatric pain scale(0-10)

Secondary outcomes

1

Description

Parents satisfaction

Timepoint

1-6-12-24 hour after procedure

Method of measurement

satisfaction score(0-3) {0=not at all satisfied, 1=not satisfied, 2= partially satisfied, 3= satisfied}

2

Description

amount of rectally received acetaminophen

Timepoint

1,6,12,24 hour after surgery

Method of measurement

total dosage(mg) and the number of times received rectal acetaminophen

3

Description

duration of analgesia provided by technique

Timepoint

hour/min after surgery

Method of measurement

interval between administration of the first dose of rectal acetaminophen and prucedure

4

Description

urine retention - bowel activity

Timepoint

1,6,12,24 hour after surgery

Method of measurement

time intrval of first urination / bowel activity from prucedure

Intervention groups

1

Description

intervention group : wound infiltration with 0/5 ml/kg bupivacaine 0/25% into the edges of the wound after fascial closure.

Category

Prevention

2

Description

control group : caudal analgesia with 1ml/kg bupivacaine
0/25%

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Mehrsima abdollahzadeh

Street address

Namjoo Street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Abdolrasol Sobhani

Street address

Emam Khomeini Blv.Top of the IRAN radiator Co.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Mehrsima Abdollahzadeh

Position

Anesthesiologist\assistant proffesor

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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