Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of incisional injection of bupivacane for pain control after pediatric lower abdominal surgery

Protocol summary

Summary

After obtaining informed consent from parents 72 children with age range of 1-12years in grades 1and 2 using ASA rating of who were candidate lower abdominal surgery coming to Tabriz Children Hospital during 1395-1396 were randomly divided into two groups.Thirty six patient in incisional injection group and 36 patients in the control group.both groups will received general anesthesia and airway management with the same method.In the first group after surgery before closure 0.5ml/kg bupivacaine 0.125%maximum 20ml will be injected into the fascia layer and in other group injection will not be used.postoperative pain score will be measured based on VAS(visual analog scale)in recovery room and then every 2 hours up to 8 hours ,and then every 4 hours up to 24 hours.the first request for analgesia, the total dose of pain medication after surgery ,the incidence and severity of postoperative complications between the two groups will be recorded

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503024041N12**
Registration date: **2017-04-03, 1396/01/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-03, 1396/01/14

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences vice chancellor for research and technology

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of incisional injection of bupivacane for pain control after pediatric lower abdominal surgery

Public title

Effect of injection of local anesthetic into the pediatric surgical site

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:1)children with age between 1-12 years with ASA class 1,2. 2)patients candidates of lower abdominal surgery Exclusion criteria:1)urgent surgery.2)concurrent surgery.3)hypersensivity to local anesthetics4)organ dysfunction.5)psychiatric dysfunction.6)chronic use of analgesics

Age

From **1 year** old to **12 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
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
Tabriz university of medical sciences vice chancellor for research and technology
Street address
Golgasht-st.Tabriz-Tabriz university of medical sciences,central building no.2-Third floor-vice chancellor research and technology
City
Tabriz
Postal code
51665-118
Approval date
2016-11-14, 1395/08/24
Ethics committee reference number
iR.TBZMED.REC.1395.883

Health conditions studied

1

Description of health condition studied
injection of local anesthetic into surgical site of inguinal hernia
ICD-10 code
N43.3 k4
ICD-10 code description
...,Hydrocele,inguinal hernia

Primary outcomes

1

Description
incisional pain
Timepoint
immediately after the intervention
Method of measurement
VAS score Questionnaire

Secondary outcomes

1

Description
The need for analgesic
Timepoint
Every 2 hours to 8 hours, then every 4 hours for 24 hours
Method of measurement
person other than researcher

Intervention groups

1

Description
intervention group: after end of surgery before closure 0.5ml/kg bupivacaine 0.125%(MYLAN company) will be injected into the fascia.
Category
Treatment - Drugs

2

Description
control group: without injection after termination of surgery.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Children`s hospital of tabriz university of medical sciences
Full name of responsible person
Dr Mahin Seidhejazi
Street address
Tabriz-Sheshgelan st.hospital children`s center
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz university of medical sciences vice chancellor for research and technology

Full name of responsible person
Dr Hasan Soleimanpour
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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
Tabriz university of medical sciences vice chancellor for research and technology

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
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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