

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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 1-12 years in grades 1 and 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

Mahin Seyedhejazi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3385 2252

Email address

seidhejazi@tbzmed.ac.ir

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) hypersensitivity to local anesthetics. 4) 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**Golgashst-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

Street address

Golgasht-st.Tabriz- Tabriz university of medical sciences,central building no.2-third floor-vice chancellor research and technology

City

Tabriz

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**

Tabriz university of medical science

Full name of responsible person

Dr Sahar Sadeghi

Position

Assistant of anesthesiology

Other areas of specialty/work**Street address**

Tabriz-university of medical science-department of anesthesiology

City

Tabriz

Postal code

00

Phone

00

Fax**Email**

dandelion1363@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz university of medical science

Full name of responsible person

Dr Mahin Seidhejazi

Position

Anesthesiologist-professor

Other areas of specialty/work**Street address**

Tabriz -Sheshgelan st.children`s hospital of tabriz university of medical science

City

Tabriz

Postal code

00

Phone

+98 41 3526 2255

Fax**Email**

seidhezazie@tbzmed.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz university of medical science

Full name of responsible person

Dr Mahin Seidhejazi

Position

professor-anesthesiologist

Other areas of specialty/work**Street address**

Tabriz children hospital

City

Tabriz

Postal code**Phone**

00

Fax**Email****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