

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of premedication with intravenous ketamine and midazolam on success and complication rates of caudal anesthesia in neonates undergoing lower abdominal surgery

Protocol summary

Summary

Infants are not able to express their pain or discomfort; moreover, they cannot work with PCA (Patient Controlled Analgesia) Pumps. Therefore, regional anesthesia techniques for controlling postsurgical pain in lower abdominal surgery are preferred. In the cases which anatomical or physiological changes increase the risk of general anesthesia, regional anesthesia methods are favored. Caudal anesthesia is a popular technic for lower abdominal surgeries below the umbilicus in children & infants. In order to decrease the chance of block failure caused unintentionally by movements during procedure, we decided to study the success & complication rates of caudal block with added intravenous premedication (midazolam and/or ketamine) In a prospective randomized single blind clinical trial, we will study 90 infants with ASA (American Society of Anesthesiologists) classes 1&2 scheduled to undergo lower abdominal surgeries in a 12 month period Patients will be divided into 3 randomized groups. 1-(control group) caudal block with bupivacaine . 2-caudal block with bupivacaine plus intravenous midazolam 0.1mg/kg 2-caudal block with bupivacaine plus intravenous midazolam 0.1mg/kg & intravenous ketamine 0.3mg/kg Absence of pain and lower limb paralysis 15 minutes after the block will be defined as is Successfulness of the block

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305164041N8**

Registration date: **2013-05-22, 1392/03/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-05-22, 1392/03/01

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

Governmental

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of premedication with intravenous ketamine and midazolam on success and complication rates of caudal anesthesia in neonates undergoing lower abdominal surgery

Public title

Effects of premedication with intravenous drugs on caudal block

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: neonate infants with ASA (American Society of Anesthesiologists) classes 1&2 scheduled to undergo lower abdominal surgeries in a 12 month period.

Exclusion criteria: existence of pain and lower limb paralysis 15 minutes after the block will be defined as failure of the block and they will be excluded.

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 Ethics Committee

Street address

Tabriz University of Medical Sciences, Golgasht street

City

Tabriz

Postal code**Approval date**

2013-04-18, 1392/01/29

Ethics committee reference number

602/4/5

Health conditions studied**1****Description of health condition studied**

Lower abdominal surgeries

ICD-10 code

K40.2

ICD-10 code description

Bilateral inguinal hernia, without obstruction or gangrene

Primary outcomes**1****Description**

pain

Timepoint

Two, 4, 6 and 8 hours postoperative

Method of measurement

Neonatal infant pain scale(NIPS)

Secondary outcomes

empty

Intervention groups**1****Description**

1-(control group) caudal block with bupivacaine

Category

Treatment - Drugs

2**Description**

intervention group:caudal block with bupivacaine plus intravenous midazolam 0.1 mg/kg & intravenous ketamine 0.3mg/kg

Category

Treatment - Drugs

3**Description**

intervention group:caudal block with bupivacaine plus intravenous midazolam 0.1mg/kg

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tabriz children Hospital

Full name of responsible person

Dr.Mahin Seyedhejazi

Street address**City**

Tabriz

Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Alireza Ostadrahimi

Street address

Tabriz University of Medical Sciences-Golgasht Ave

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

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 Sciences

Full name of responsible person

Dr. Mahin Seyedhejazi

Position

Associate Professor of Anesthesia

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

Tabriz Children Hospital

City

Tabriz

Postal code**Phone**

+98 41 1477 3957

Fax**Email**

seidhejazie@yahoo.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mahin Seyedhejazi

Position

Associate Professor of Anesthesia

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

Tabriz Children Hospital

City

Tabriz

Postal code**Phone**

+98 41 1477 3957

Fax**Email**

seidhejazie@yahoo.com

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mahin Seyedhejazi

Position

Associate Professor of Anesthesia

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

Tabriz Children Hospital

City

Tabriz

Postal code**Phone**

+98 41 1477 3957

Fax**Email**

seidhejazie@yahoo.com

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*