

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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**

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**Postal code****Phone**

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seidhejazie@yahoo.com

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

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**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*