

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of the addition of dexmedetomidine to low dose bupivacaine on the duration of anaesthesia in the caudal block after lower abdominal surgeries

#### Protocol summary

##### Summary

Aim: assessment of the effect of the addition of dexmedetomidine to low dose bupivacaine on the duration of anesthesia in the caudal block after lower abdominal surgeries. Target population: one to 6-year-old children who were class ASA 1 and candidates for lower abdominal surgeries and have been referred to the children hospital of TUMS. Inclusion criteria: class ASA 1 children who were between 1 and 6 years old and were candidates for lower abdominal surgeries and caudal block. Exclusion criteria: developmental delay hx; hemostasis disorders; antiplatelet medication use; sensitivity to the used drugs in the study; local infection in the caudal block site or congenital anomalies; pre-operational need for analgesics. Interventions: two-hundred children were randomly divided into two groups. For all patients, 33 mg/kg bolus infusion of methyl prednisolone was administered in 15 min. For control group, the caudal block was done using 1 mg/kg of bupivacaine+ normal saline (1 cc/kg volume), and in the study group this procedure was performed using 1 mg/kg of bupivacaine + 1 micro/kg of dexmedetomidine (1 cc/kg volume) The pain scale after surgery, the first time that the patients need analgesics and their dose in the first 24 hours, the total amount of analgesics used in 24 hours and the time of voluntary leg movements and urination were assessed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017080513947N8**

Registration date: **2017-08-15, 1396/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-08-15, 1396/05/24

##### Registrant information

###### Name

Atta Mahdkhah

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1332 6196

###### Email address

mshimia@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2017-04-21, 1396/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of the addition of dexmedetomidine to low dose bupivacaine on the duration of anaesthesia in the caudal block after lower abdominal surgeries

##### Public title

The effect of the addition of dexmedetomidine to low dose bupivacaine on the duration of anaesthesia in the

caudal block after lower abdominal surgeries

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: class ASA 1 children who were between 1 and 6 years old and were candidates for lower abdominal surgeries and caudal block. Exclusion criteria: developmental delay hx; hemostasis disorders; antiplatelet medication use; sensitivity to the used drugs in the study; local infection in the caudal block site or congenital anomalies; pre-operational need for analgesics.

### **Age**

From **1 year** old to **6 years** old

### **Gender**

Both

### **Phase**

2-3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **200**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee and Research, Tabriz University of Medical Sciences

##### **Street address**

Iran, Tabriz, Golgasht Street, Ethics Committee and Research, Tabriz University of Medical Sciences

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2017-05-08, 1396/02/18

#### **Ethics committee reference number**

IR.TBZMED. REC.1396.118

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Local anaesthetics

#### **ICD-10 code**

Y48.3

#### **ICD-10 code description**

Anaesthetics and therapeutic gases

## **Primary outcomes**

### 1

#### **Description**

The pain scale after surgery

#### **Timepoint**

4, 8, 12, 24 h after of operation

#### **Method of measurement**

Evaluation of the pain scale after surgery with FLACC behavioral tool for children under 3 years old and Baker-Wong FACES rating scale for children older that 3 years

## **Secondary outcomes**

### 1

#### **Description**

The time of voluntary leg movements and urination were assessed.

#### **Timepoint**

After operation

#### **Method of measurement**

by expert nurse

### 2

#### **Description**

The first time that the patients need analgesics and their dose in the first 24 hours, the total amount of analgesics used in 24 hours

#### **Timepoint**

24h

#### **Method of measurement**

after admission in ward and by expert nurse

## **Intervention groups**

### 1

#### **Description**

For all patients, 33 mg/kg bolus infusion of methyl prednisolone was administered in 15 min. For control group, the caudal block was done using 1 mg/kg of bupivacaine+ normal saline (1 cc/kg volume)

#### **Category**

Treatment - Drugs

### 2

#### **Description**

For all patients, 33 mg/kg bolus infusion of methyl prednisolone was administered in 15 min. In the study

group this procedure was performed using 1 mg/kg of bupivacaine + 1micro/kg of dexmedetomidine (1 cc/kg volume)

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Tabriz University of Medical Sciences, Children hospital

**Full name of responsible person**

Dariush Sheikhzadeh

**Street address**

Tabriz, Sheshkalan street, Children hospital

**City**

Tabriz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dariush Sheikhzadeh

**Street address**

Tabriz University of Medical Sciences, Golgasht street

**City**

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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

**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

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**Position**

Assistant Professor

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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*