

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Cardiovascular effects of adding epinephrine to local anesthetics in children under the caudal epidural block for subumbilical surgery

#### Protocol summary

##### Study aim

Cardiovascular effects Add epinephrine to local anesthetics in children under the caudal epidural block for subumbilical surgery.

##### Design

People will be divided into two groups according to a random number table

##### Settings and conduct

A total of 60 children under the age of six years undergoing general anesthesia undergoing cervical cancer surgery. People will be divided into two groups according to random numbers. Drug syringes are being prepared by the anesthetic professors of the children. Drugs for blocking will be done by children's anesthetic flashing.

##### Participants/Inclusion and exclusion criteria

Children under the age of six years undergoing subumbilical surgery (including lower abdominal surgery and urinary tract) under general anesthesia

##### Intervention groups

Cardiovascular effects in patients with caudal block with local anesthetic and epinephrine

##### Main outcome variables

ECG Variation,pulse Rate,blood Presuer.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100527004041N15**

Registration date: **2018-07-12, 1397/04/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-12, 1397/04/21**

Update count: **0**

##### Registration date

2018-07-12, 1397/04/21

#### 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

seidhejazie@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2018-09-22, 1397/06/31

##### Actual recruitment start date

2018-03-21, 1397/01/01

##### Actual recruitment end date

2018-09-22, 1397/06/31

##### Trial completion date

empty

#### Scientific title

Cardiovascular effects of adding epinephrine to local anesthetics in children under the caudal epidural block for subumbilical surgery

#### Public title

cardiovascular effects of epinephrine in pediatric caudal block

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Children under the age of 6 years undergoing sub umbilical surgery ;;

##### Exclusion criteria:

Children aged 6 or older Surgeries that can not be used with a caudal block

IR.TBZMED.REC.1396.1236

### Age

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

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **60**

Actual sample size reached: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Accidental randomization to intervention groups and control groups, Patients, the person responsible for recording vital signs and the person analyzing the data will be unaware of the addition or not of an epinephrine.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Pediatric Anesthesia Fellowship and Experienced Anesthetist Nurse will be responsible for measuring these symptoms. Patients are the person responsible for recording vital signs and the person analyzing the data are unaware of whether or not to perform airway suction.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Etics committee of Tabriz University of Medical Sciences

##### Street address

Golgasht Ave,Tabriz University of Medical science

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614766

##### Approval date

2018-03-17, 1396/12/26

##### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

Patients undergo subumblical surgery

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

ECG Exchange

#### Timepoint

Measurement of heart rate Blood pressur and ECG in minutes are 0, 1, 5, and 20

#### Method of measurement

Measurement by Digital Beatitude Monitor

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: A group of children aged from one to six years undergoing subumblical surgery which is used to treat post-operative anesthesia of the caudal block, and the epinephrine agent is given as an add-on to local anesthetic drugs.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

### 2

#### Recruitment center

##### Name of recruitment center

Tabriz Children Hospital

##### Full name of responsible person

Mahin .Seidhejazie

##### Street address

Sheshgelan Ave,Tabriz Children Hospital

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##### Postal code

57147\_83732

##### Phone

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**Email**

seidhejazie@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mahmoodpoor.ata

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Golgasht Ave.Tabriz Univercity of Medical Since

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info@medfac.tbzmed.ac.ir

**Web page address**

**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**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Tohid.Karami

**Position**

Fellowship of Pediatric Anesthesia

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

#### Contact

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Tabriz University of Medical Sciences

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**Position**

professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

#### Contact

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**Position**

professor

**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

### **Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

### **Study Protocol**

Yes - There is a plan to make this available

### **Statistical Analysis Plan**

No - There is not a plan to make this available

### **Informed Consent Form**

Yes - There is a plan to make this available

### **Clinical Study Report**

Yes - There is a plan to make this available

### **Analytic Code**

Not applicable

### **Data Dictionary**

Not applicable

### **Title and more details about the data/document**

We are going to publish all in paper

### **When the data will become available and for how long**

In the end of study

### **To whom data/document is available**

Every one who read the paper

### **Under which criteria data/document could be used**

If the data is needed to be used for further analysis, only the study designer has access to the codes and patients information. If the data is going to be used in another study, a proposal (in which the goals of study are established) should be registered and ethics code must be received.

### **From where data/document is obtainable**

From the paper

### **What processes are involved for a request to access data/document**

No need for special process

### **Comments**