

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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

seidhejazi@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

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 scince

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2018-03-17, 1396/12/26

Ethics committee reference number

IR.TBZMED.REC.1396.1236

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

City

Tabriz

Province

East Azarbaijan

Postal code

57147_83732

Phone

+98 41 3526 2262

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

Street address

Golgasht Ave.Tabriz Univercity of Medical Since

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2262

Email

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

Street address

Sheshgelan Ave,Tabriz Childeren Hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2262

Email

karami.tohid@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahin.Seidhejazie

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Pediatric Anesthesia

Street address

Sheshgelan Ave,Tabriz Childeren Hospital

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2262

Email

seidhejazie@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mahin.Seidhejazie

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatric Anesthesia

Street address

Sheshgelan Ave, Tabriz Childeren Hospital

City

Tabriz

Province

East Azarbaijan

Postal code

57147_83724

Phone

+98 41 3526 6911

Email

seidhejazie@tbzmed.ac.ir

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