

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of hemodynamic changes during general anesthesia in children with or without caudal anesthesia using ropivacaine.

Protocol summary

Study aim

Investigation of hemodynamic changes between general anesthesia and caudal anesthesia in children.

Design

Clinical trial with intervention and control groups, with parallel groups, double-blind, randomized, sample of 40 patients. Randlist software was used for randomization.

Settings and conduct

All children who are candidates for lower abdominal surgery at Tabriz pediatric hospital will be included in this study. Patients are randomly assigned to two intervention and control groups. Lidocaine, propofol, and ropivacaine will be used in the intervention group, and only lidocaine and propofol will be used in the control group to compare the hemodynamics effects in these patients. In this study, the patient and anesthesia nurse and one of the anesthesiologist are blinded to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All children from 6 months to 7 years, ASA grade With class I&II, Candidate for lower abdominal surgery. Exclusion criteria: Having any neuropathy, History of allergy to anesthetics.

Intervention groups

Intervention group: In this group, the patient was anesthetized with 1 mg / kg lidocaine and 3.5 to 4.5 mg / kg propofol and after induction of anesthesia, before the start of surgery, caudal anesthesia with 0.2% ropivacaine, 1 micro-gram per kilogram will be performed. Control group: In this group, anesthesia will be induced with 1 mg / kg lidocaine and 3.5 to 4.5 mg / kg propofol.

Main outcome variables

Systolic and diastolic blood pressure, mean arterial pressure (MAP), heart rate, saturation of peripheral oxygen.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100527004041N22**

Registration date: **2020-06-10, 1399/03/21**

Registration timing: **prospective**

Last update: **2020-06-10, 1399/03/21**

Update count: **0**

Registration date

2020-06-10, 1399/03/21

Registrant information

Name

Mahin Seyedhejazi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of hemodynamic changes during general anesthesia in children with or without caudal anesthesia using ropivacaine.

Public title

Investigation of hemodynamic changes between general anesthesia and general caudal anesthesia in children.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All children from 6 months to 7 years ASA grade With class I&II Candidate for lower abdominal surgery

Exclusion criteria:

Having any neuropathy History of allergy to anesthetics

Age

From **6 months** old to **7 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to intervention and control groups will be performed using the random numbered table technique via Randlist online software, individually for patients. In this study, patients were randomly divided into two groups via simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Two anesthesiologists will be involved in the study An anesthesiologist No. 1 has induced anesthesia,that it will be applied as general anesthesia for one group and caudal for another.Then anesthesiologist No. 1 who is aware of patients codes and injections leave the operation room and anesthesiologist NO.2 and The anesthesia nurse, who is responsible for collecting information and variables from the patient and is unaware of the type of prescribed drug, fills in the checklist during surgery and recovery section .The patient is also unaware of the type of Injecting drug.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Golgasht Street

City

Tabriz

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East Azarbaijan

Postal code

5183915881

Approval date

2020-06-07, 1399/03/18

Ethics committee reference number

IR.TBZMED.REC.1399.214

Health conditions studied

1

Description of health condition studied

Hemodynamic changes after general anesthesia and caudal anesthesia.

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Systolic and diastolic blood pressure

Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery section until discharging,every 10 minutes.

Method of measurement

Mercury barometer

2

Description

Mean arterial pressure(MAP)

Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery section until discharging,every 10 minutes.

Method of measurement

Mercury barometer

3

Description

Heart rate

Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery section until discharging,every 10 minutes.

Method of measurement

Counting in each minutes

4

Description

Saturation of peripheral oxygen

Timepoint

From the beginning of anesthesia to 30th minute, every 5 minutes and after that every 15 minutes and in recovery section until discharging, every 10 minutes.

Method of measurement

Via the Pulse Oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the patient was anesthetized with 1 mg / kg lidocaine and 3.5 to 4.5 mg / kg propofol and after induction of anesthesia, before the start of surgery, caudal anesthesia with 0.2% ropivacaine, 1 micro-gram per kilogram will be performed.

Category

Treatment - Drugs

2

Description

Control group: In this group, anesthesia will be induced with 1 mg / kg lidocaine and 3.5 to 4.5 mg / kg propofol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Operating room, Tabriz Children Hospital

Full name of responsible person

Dr. Mahin Seyedhejazi

Street address

Tabriz pediatric hospital, sheshgelan street, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Vice chancellor for research, Daneshgah street, Tabriz

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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

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

Dr. Mahin Seyedhejazi

Position

Anesthesiologist/Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Tabriz pediatric hospital, sheshgelan street, Tabriz

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after making peoples unrecognizable.

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Documents will be available for people working in academic institutions and also people working in businesses.

Under which criteria data/document could be used

There will be no specific limitations to the utilization of the data

From where data/document is obtainable

Dr .Mahin Seyedhejazi, Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran ,Phone+98 413 3341994, Fax+98 41 33341994 , seidhejazie@tbzmed.ac.ir

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

Applicants will access the data from the present study by sending an email to the responsible author for a maximum of one week.

Comments