Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

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

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% rupivacaine, 1 micro-gram per kilogram will be performed. Control group:In this group, anesthesia will be inducted 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 rupivacaine.

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
Province
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 15minutes 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% rupivacaine, 1 micro-gram per kilogram will be performed.
Category
Treatment - Drugs

2

Description
Control group:In this group, anesthesia will be inducted 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr Abolghasem Joyban
Street address
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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Person responsible for updating data

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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