

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of hemodynamic changes after caudal anesthesia with intravenous dexamethasone.

Protocol summary

Study aim

Evaluation of hemodynamic changes after caudal anesthesia with intravenous dexamethasone

Design

100 patients that meet the inclusion criteria will be selected. After surgery and when the patient is discharged from anesthesia, the intervention group will receive dexamethasone and the control group will receive distilled water. The study is a randomized, double-blind, placebo-controlled clinical trial.

Settings and conduct

Patients in pediatric hospital operating room will be randomly divided into two groups based on a random number table. The intervention group received 0.5 mg / kg dexamethasone and the control group received 0.5 mg / kg distilled water (similar to dexamethasone) at the start of anesthesia with bupivacaine. Given that the study is double-blind. Both dexamethasone and distilled water (similar to dexamethasone) will be administered to the required number by the planter every morning prior to the start of surgery. Envelope A contains a syringe containing dexamethasone and Envelope B contains distilled water. Each patient will receive these envelopes on the basis of an A or B code, provided by the anesthesiologist who is unaware of the type of drug as the patient is.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages between 1 to 8 years old, candidate for elective lower abdomen surgery
Exclusion criteria: Allergy to Anesthetic Drugs, Allergic to dexamethasone, Previous Neurological Diseases, vertebral column Anomalies

Intervention groups

Intervention group: These patients will receive 0.5mg intravenous dexamethasone while inducing anesthesia with 0.2% bupivacaine at a dose of 1ml/kg. Control group: This group is similar to the intervention group, only distilled water will be injected with dexamethasone.

Main outcome variables

Evaluation of dexamethasone infusion on hemodynamic changes such as systolic and diastolic blood pressure, MAP, heart rate, petco2 and spo2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100527004041N20**

Registration date: **2020-01-02, 1398/10/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-02, 1398/10/12**

Update count: **0**

Registration date

2020-01-02, 1398/10/12

Registrant information

Name

Mahin Seyedhejazi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3385 2252

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seidhejazie@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of hemodynamic changes after caudal anesthesia with intravenous dexamethasone.

Public title

The effect of intravenous dexamethasone injection on hemodynamic changes after caudal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Parent consent to participate in the study Age between 1to8 years old Candidate for elective lower abdominal surgery Candidate for elective lower limb surgery

Exclusion criteria:

Allergies to anesthesia drugs Allergies to dexamethason Coagulation abnormalities Previous neurological disease Vertebral anomalies Any infection at the injection site

Age

From **1 year** old to **8 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

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

The anesthesiologist who has responsible for the patients management of anesthesia will administer the medicine(s) via coded syringes had been prepared previously and will not aware of the injected drug(dexamethasone or ketamin), and anesthesia nurse who is responsible for collection of patients information and study variables and is unaware of the administered drug will record the check- list during surgery and in the recovery.Also the patient is unaware of the injected medicine.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Faculty of Medicine, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2019-11-26, 1398/09/05

Ethics committee reference number

IR.TBZMED.REC.1398.866

Health conditions studied**1****Description of health condition studied**

Hemodynamic changes after 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

Method of measurement

Mercury barometer

Secondary outcomes**1****Description**

Mean arterial pressure(MAP)

Timepoint

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes

Method of measurement

Mercury barometer

2

Description

Heart rate

Timepoint

From the beginning of anesthesia to 30th minute, every 5 minutes and after that every 15 minutes

Method of measurement

Counting in each minutes

3

Description

Partial pressure of end tidal of carbondioxide

Timepoint

From the beginning of anesthesia and then every 30 minutes

Method of measurement

Using the Copnograph

4

Description

Saturation of peripheral oxygen

Timepoint

From the beginning of anesthesia and then every 30 minutes

Method of measurement

Via the Pulse Oximeter

Intervention groups

1

Description

Intervention group: these patients will receive 0.5 mg intravenous dexamethasone while inducing anesthesia with 0.2% bupivacaine at a dose of 1 ml / kg

Category

Treatment - Drugs

2

Description

Control group: these patients will receive 0.5 mg of distilled water (exactly similar to dexamethasone) while inducing anesthesia with bupivacaine 0.2% at a dose of 1 ml / kg.

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

Sheshgelan St , Tabriz Children Hospital, Tabriz city

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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

Associate Professor Of Anesthesia

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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 collected deidentified IPD, IPD collected for the primary outcome measure are to be shared

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

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

Correspondence through email only .

Comments