Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the Impact of caudal block anesthesia on the postoperative complications of hypospadias repair in children 6 months to 15 years old: a randomized clinical trial

Protocol summary

Study aim
Evaluation of the effect of the caudal epidural block on the outcome of hypospadias repair in boys 6 months to15 years.

Design
Two arm parallel-group double-blinded randomized clinical trial on 60 patients.

Settings and conduct
Boys with hypospadias will be assessed for eligibility. The study will take place at Al-Zahra Hospital, Isfahan, Iran. The patients will be randomized into two groups. In the case group, the caudal block will be performed following the surgery in addition to the general anesthesia. In the control group, only general anesthesia will be performed. The caudal block will be performed after the surgeon leaves the operating room.

Participants/Inclusion and exclusion criteria
Boys aged 6 months to 15 years who are candidates for hypospadias repair surgery.

Intervention groups
60 patients will be recruited in the study. The patients will be randomized into two groups: patients who underwent general anesthesia alone (control) and patients who underwent general anesthesia and caudal block anesthesia (case).

Main outcome variables
The complication rate of hypospadias repair

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200124046243N1**
Registration date: **2021-05-01, 1400/02/11**
Registration timing: **registered_while_recruiting**
Last update: **2021-05-01, 1400/02/11**
Update count: **0**

Registration date
2021-05-01, 1400/02/11

Registrant information
Name
Saeid Haghdani
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-12-31, 1400/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Impact of caudal block anesthesia on the postoperative complications of hypospadias repair in children 6 months to 15 years old: a randomized clinical trial

Public title
caudal block anesthesia in hypospadias repair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

boys candidate for hypospadias repair age between 6 month and 15 years

Exclusion criteria:

two stage hypospadias repair history of previous surgery history of spinal cord anomaly history of diabet history of other congenital defects history of bleeding diathesis history of drug allergy to bupivacaine not using anticoagulants or antiplatelets

Age

From **6 months** old to **15 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomized into two groups. Randomization will be performed by Random Allocation Software version 1.0.0. this software has been developed by M. Saghaei, MD, department of anesthesia, Isfahan University of Medical Science, Isfahan, Iran. (more about the software: https://pubmed.ncbi.nlm.nih.gov/15535880/). Blocks with an equal size of 6 will be used (View menu > Options > Equal size> 6). After every block, the number of participants in each group would be equal. The researcher will contact the patients' parents and the patient will receive a closed envelope that contains the code based on the allocated group. The closed envelope will be given to the anesthesiologist in the operating room. The anesthesiologist will perform the anesthesia based on the code. Thus, the surgeon and the patients will not have information about the group allocation. (Download the software from here: https://mahmoodsaghaei.tripod.com/Softwares/randalloc.html#Options)

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blinding will be performed for the participants and the surgeon. The closed envelope will be given to the anesthesiologist in the operating room. The caudal block will be performed after the operation based on the code of the patients in the envelope and the surgeon and the patients will not have information about the group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Isfahan university of Medical Science

Street address

Hezar jarib Ave

City

Isfahan

Province

Isfehan

Postal code

1234567890

Approval date

2019-05-19, 1398/02/29

Ethics committee reference number

IR.MUI.MED.REC.1398.080

Health conditions studied

1

Description of health condition studied

hypospadias

ICD-10 code

Q54

ICD-10 code description

Hypospadias

Primary outcomes

1

Description

hypospadias surgery complications

Timepoint

1st week, 1st Month and 6th month after surgery

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Caudal Epidural Block anesthesia plus general anesthesia. caudal anesthesia is performed, using small needle (24-27 G) by injecting 0.5 mg/Kg of 0.125% Marcaine. Induction of anesthesia is done with thiopental sodium (5 mg/kg), atracurium (0.6 mg/kg), fentanyl (2 microg/kg), and morphin (0.1 mg/kg).During

surgery, anesthesia is continued with 1.25 % isofluran gas.

Category

Treatment - Other

2

Description

Control group: general anesthesia

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Farshid Alizadeh

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Sofeh street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

saeid haghdani

Position

consultant

Latest degree

Specialist

Other areas of specialty/work

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available