

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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 to 15 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

Country

Iran (Islamic Republic of)

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+98 21 81161

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saeed_haghdani@yahoo.com

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 diabetes 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

Isfahan

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
Street address
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
Bahram Nasr
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1234567890
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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
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consultant
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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