

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Evaluation and comparison of the effect of two methods of pudendal anesthesia and dorsal penile nerve block (DPNB) on reducing pain after neonatal circumcision

#### Protocol summary

##### Study aim

Determining and comparing the mean pain score based on the neonatal infant pain scale (NIPS ) before circumcision between the two groups of pudendal and dorsal penile nerve block anesthesia Determination and comparison of mean pain score based on NIPS neonatal infant pain scale six hours after circumcision between the two groups of pudendal and dorsal penile nerve block anesthesia

##### Design

The trial consists of two double-blind study groups in which the researcher and the patient are unaware of the patient's anesthesia and are randomized. Excel software rand function will be used for randomization.phase 3 with 88 patients.

##### Settings and conduct

After obtaining consent, patients are randomly divided into two groups: pudendal anesthesia and dorsal penile nerve block and are circumcised in the operating room of Imam Hossein Hospital. Immediately after the surgery and six hours after surgery, the amount of pain of the patient will be examined and registered. The patient and the results recorder and data analyzer will not be aware of the anesthesia.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Infants between 1 and 3 months who have the consent of parents to participate in the project  
Exclusion criteria: People under 1 month and over 3 months; parental dissatisfaction with either circumcision or plan; children with hypospadias, , fever, underlying disease or jaundice

##### Intervention groups

Children between the ages of one and three months undergoing circumcision and receiving anesthesia by the pudendal method. Children between the ages of one and three months who undergo circumcision, and receive anesthesia by the dorsal penile nerve block method.

#### Main outcome variables

pain score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201110049338N1**

Registration date: **2021-02-20, 1399/12/02**

Registration timing: **prospective**

Last update: **2021-02-20, 1399/12/02**

Update count: **0**

##### Registration date

2021-02-20, 1399/12/02

##### Registrant information

##### Name

Ali Fazeli

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3625 8850

##### Email address

alifazeli@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-10, 1399/12/20

##### Expected recruitment end date

2022-02-09, 1400/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation and comparison of the effect of two methods of pudendal anesthesia and dorsal penile nerve block (DPNB) on reducing pain after neonatal circumcision

**Public title**  
Evaluation and comparison of the effect of two methods of pudendal anesthesia and dorsal penile nerve block (DPNB) on reducing pain after neonatal circumcision

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The children should be in defined age range They should be candidates for local anesthesia circumcision They shouldn't have underlying disease  
**Exclusion criteria:**

**Age**  
From **1 month** old to **3 months** old

**Gender**  
Male

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **88**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization method is simple and individuals are randomly divided into two different clusters of anesthesia after obtaining a random number and the operation will be performed according to which group each patient is in. MATLAB R 2019 software is used. rand i command code is used. The person who randomizes is unaware of the type of group, which one belongs to which code

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The patient doesn't know how he becomes anesthetized.  
The data analyzer doesn't know about the procedure.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Hear jarib

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2020-10-08, 1399/07/17

**Ethics committee reference number**

IR.MUI.MED.REC.1399.586

## Health conditions studied

### 1

**Description of health condition studied**

Reducing pain after circumcision

**ICD-10 code**

**ICD-10 code description**

## Primary outcomes

### 1

**Description**

Pain scal after circumcision

**Timepoint**

0 and 6 hours after circumcision

**Method of measurement**

neonatal infant pain scale' score

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: pain scale with pudendal anesthesia method in patients who undergo circumcision with lidocaine immediately after surgery and six hours after surgery

**Category**

Rehabilitation

### 2

**Description**

Intervention group: pain scale with dorsal penile nerve block anesthesia method in patients who undergo

circumcision with lidocaine immediately after surgery and six hours after surgery

**Category**

Rehabilitation

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Imam Hossein hospital

**Full name of responsible person**

Dr. Mehrdad Memarzade

**Street address**

Imam Khomeini

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+98 31 3386 6266

**Email**

emamhossein\_hospital@mui.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Anooshe Zargar kharrazi

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**Phone**

+98 31 3668 8138

**Email**

research@mui.ac.ir

**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**

دکتر علی فاضلی

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatric surgery

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Hezar jarib

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**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr.Ali Fazeli

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatric surgery

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

Pediatric surgery

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**Email**

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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**

Pain score of each patient after discovering patient in details

**When the data will become available and for how long**

3 months after publication

**To whom data/document is available**

Only for researches in Universities and scientific institutions.

**Under which criteria data/document could be used**

The person should be university faculty and just for citation

**From where data/document is obtainable**

Fazeli\_fazeli2011@yahoo.com

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

After sending the request to the author's email and confirming the identity of the applicant, the documents will be sent by a week to him/her.

**Comments**