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)

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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 Scienses

Street address

Hear jarib

City

Isfahan

Province

Isfehan

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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emamhossein_hospital@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

دکتر علی فاضلی

Position

Assistant professor

Latest degree

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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

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 jost 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