

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of dexamethasone on postoperative analgesia in the children undergoing hypospadias repair

Protocol summary

Summary

Management of post operative pain in the children who have undergone hypospadias repair accounts for optimized surgery outcomes and improved patients' satisfaction. Thus, various studies have widely investigated the best approaches for this pain management. In this double-blind, randomized clinical trial, 42 patients undergoing surgical treatment of hypospadias were divided into a case (n=23) and a control (n=19) group to receive either IV dexamethasone 0.5 mg/kg or placebo (normal saline) during the operation. Penile block was also performed in both groups using Bupivacaine 0.5% (1mg/kg) at the end of the procedure. FLACC pain scoring system was used for evaluation of post operative pain. Patients aged between 1- 6 years old who had distal hypospadias. Patients with other types of hypospadias or those with other associated congenital anomalies were excluded from study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030416840N1**

Registration date: **2014-06-08, 1393/03/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-08, 1393/03/18

Registrant information

Name

Behnam Nasihatkon

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 1006

Email address

nasihatb@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2011-03-01, 1389/12/10

Expected recruitment end date

2013-03-01, 1391/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of dexamethasone on postoperative analgesia in the children undergoing hypospadias repair

Public title

Efficacy of dexamethasone on postoperative analgesia in the children undergoing hypospadias repair

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients aged between 1- 6 years old who had distal hypospadias. Exclusion criteria: patients with other types of hypospadias or those with other associated congenital anomalies

Age

From **1 year** old to **6 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 42

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences(Vice-Chancellor for research)

Street address

Shiraz university of Medical Sciences- Zand Blvd. ,Shiraz, Iran

City

Shiraz

Postal code

Approval date

2014-05-10, 1393/02/20

Ethics committee reference number

2014-201

Health conditions studied

1

Description of health condition studied

Distal hypospadias

ICD-10 code

Q54.0

ICD-10 code description

Hypospadias, balanic

Primary outcomes

1

Description

Post-operative pain

Timepoint

in the recovery room and after 2, 6, 12, and 24 hours

Method of measurement

FLACC pain scoring system

Secondary outcomes

empty

Intervention groups

1

Description

The patients of the intervention group received 0.5 mg/kg dexamethasone during operation.

Category

Treatment - Drugs

2

Description

The patients in control group got the same volume of normal saline during operation.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Mehdi Shirazi M.D.

Street address

Namazi sq. , Zand blvd , Shiraz, Iran

City

Shiraz

2

Recruitment center

Name of recruitment center

Shahid Faghihi Hospital

Full name of responsible person

Mehdi Shirazi M.D.

Street address

Beside school of medicine, Zand blvd, Shiraz, Iran

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, Vice-Chancellery of Research and Technology

Full name of responsible person

Dabaghmanesh MH M.D.

Street address

Shiraz University of Medical Sciences, Zand blvd. , Shiraz , Iran

City

Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Shiraz University of Medical Sciences, Vice-Chancellery of Research and Technology
Proportion provided by this source
 100
Public or private sector
 empty
Domestic or foreign origin
 empty
Category of foreign source of funding
 empty
Country of origin
Type of organization providing the funding
 empty

Person responsible for general inquiries

Contact
Name of organization / entity
 Shiraz University of Medical Sciences
Full name of responsible person
 Behnam Nasihatkon
Position
 Resident of Urology
Other areas of specialty/work
Street address
 Shiraz University of Medical Sciences, Shiraz, Iran
City
 Shiraz
Postal code
Phone
 +98 71 1628 6587
Fax
Email
 nasihatb@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
 histomorphometry and stereology research center, shiraz university of medical sciences
Full name of responsible person
 Mehdi Shirazi
Position

Associate professor
Other areas of specialty/work
Street address
 shiraz university of medical sciences, shiraz, Iran
City
 Shiraz
Postal code
Phone
 +98 917 711 1354
Fax
Email
 shirazim@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
 Shiraz University of Medical Sciences
Full name of responsible person
 Behnam Nasihatkon
Position
 Resident of Urology
Other areas of specialty/work
Street address
 Shiraz University of Medical Sciences, Zand blvd, Shiraz, Iran
City
 Shiraz
Postal code
 1433671348
Phone
 +98 71 1230 5410
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
 empty
Study Protocol
 empty
Statistical Analysis Plan
 empty
Informed Consent Form
 empty
Clinical Study Report
 empty
Analytic Code
 empty
Data Dictionary
 empty