

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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

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**Name of organization / entity**  
Shiraz University of Medical Sciences  
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Resident of Urology  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*