

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

A Comparative study on Effect of two Types of Urine drainage cares (Open/closed system) on acute complications after Hypospadias repair in 6-36 months old children

Protocol summary

Summary

This randomized, single-blind, single-center clinical trial has been conducted on children admitted to surgical clinic at Mofid children's hospital over the year 2011-2012 in order to compare the effectiveness of two urine drainage care methods (open/close) on acute complications of Hypospadias repair and the study was continued for 15 months. The age between 6-36 months and being diagnosed with mid-shaft and distal Hypospadias and Underwent the TIP procedure (Tubularized Incised Plate Urethroplasty) were among inclusion criteria and kidney disease, diabetes mellitus, coagulation defects and immune deficiency, have been considered as exclusion criteria. 108 children in confirmation with inclusion criteria have been randomly split in 2 groups of 54. Groups were tried to be similar in terms of severity of abnormality, surgical history and chordee condition. The studied intervention method were open urine drainage care (double-nappy care method). In control group urine discharged by open method using urine bag. Urine volume over 24h, patency of the new urethra, bleeding and edema in surgical site, urinary tract infection, wound infection, wound dehiscence, removal of catheter by patient, level of child restlessness determined by amount of analgesics received as the primary outcome measure were all observed and measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014010816142N1**
Registration date: **2014-02-03, 1392/11/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-03, 1392/11/14

Registrant information

Name

Marzieh Fatemian

Name of organization / entity

Shaheed Beheshti University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2010-12-26, 1389/10/05

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative study on Effect of two Types of Urine drainage cares (Open/closed system) on acute complications after Hypospadias repair in 6-36 months old children

Public title

The effect of double nappy technique on acute complications of urethroplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Criteria for inclusion: Being diagnosed with mid-shaft and distal hypospadias; Age between 6-36 months; Underwent the TIP procedure (Tubularized Incised Plate Urethroplasty); Parental consent
Criteria for exclusion: Age below 6 month or older than 36 month; other than TIP procedure; Being diagnosed with hypospadias other than mid-shaft and distal; Accompanied by other diseases (Kidney disease, Diabetes Mellitus, coagulation defects, immune deficiency); Parents did not consent

Age

To 3 years old

Gender

Male

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: 108

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for Research Shahid Beheshti
University of Medical sciences

Street address

Chamran Highway - Evin

City

Tehran

Postal code

Approval date

2010-10-31, 1389/08/09

Ethics committee reference number

89-01-119-7088

Health conditions studied

1

Description of health condition studied

Hypospadias

ICD-10 code

Q54.1

ICD-10 code description

Hypospadias, penile

Primary outcomes

1

Description

removal of catheter by patient

Timepoint

every 3h for 7 days

Method of measurement

observations are recorded in patient's information sheet

2

Description

level of child restlessness

Timepoint

every 3h for 7 days

Method of measurement

determined by amount of analgesics received and recorded patient's information sheet

3

Description

Catheter irrigation if needed

Timepoint

if needed

Method of measurement

observed and recorded in patient's information sheet

4

Description

patency of the new urethra

Timepoint

every 3h for 7 days

Method of measurement

observations are recorded in patient's information sheet

5

Description

Urine volume over 24h

Timepoint

every 3h for 7 days

Method of measurement

observations are recorded in patient's information sheet

6

Description

urinary tract infection

Timepoint

before surgery and after removal of catheter

Method of measurement

urine culture and recorded in patient's information sheet

7

Description

wound dehiscence

Timepoint

daily for 7 days

Method of measurement

observed and recorded in patient's information sheet

8

Description

edema and bleeding in surgical site

Timepoint

every 3h for 7 days

Method of measurement

observed and recorded in patient's information sheet

9

Description

wound infection in surgical site

Timepoint

daily for 7 days

Method of measurement

observed and recorded in patient's information sheet

Secondary outcomes

1

Description

strictures

Timepoint

at the time of catheter removal, one month, three month, six month after surgery

Method of measurement

observations are recorded in patient's information sheet

2

Description

fistulas

Timepoint

at the time of catheter removal one month, three month, six month after surgery

Method of measurement

observations are recorded in patient's information sheet

Intervention groups

1

Description

Intervention group with open urine drainage care (double nappy care method) after-surgery, the following procedure has been used: 1-In the central area of the first diaper a 3 by 3 cm two intersecting lines has been marked and cut. With a scissor two diagonal lines will be

cut providing 4 triangles 2- 8 adhesive tapes (8cm in length by 1.5 cm in width) are needed 3- Fold one of the triangles inwardly and fix it with tape 4- The same procedure should be applied to the rest of three triangles. Cover lines between triangle with tape In order to avoid any contact with surgical site . 5- Lubricate around the hole in order to minimize the contact with surgical area. 6- Diapering should be done in such a way that the hole be in the front. 7-The tip of the stent carefully passes through the hole in the nappy. 8-First diaper should be fixed on child body by applying tapes. 9-Then, the second diaper with a larger size has been used. The free end of stent catheter has been positioned carefully and kinking, twisting or blocking were extremely avoided. 10- The inner diaper should be changed right after each defecation. The outer one should be changed upon contamination or wetting. There was no need to restrict child's movement and mother could hang the child. Mother learned how to change and weight the diaper. Evaluation indicators should be recorded after surgery through accurate observations.for 7 days and each 3 hrs (the dried diapers were weighted and again after getting wet and urine output measured and recorded).

Category

Prevention

2

Description

Control group, with close urine drainage care after surgery the following procedure has been used : the dripping stent has been attached to a urine bag and it was fixed by hanger bar on railing's bed. The stent catheter was fixed on lower abdomen by adhesive tape . It should be noted that kinking, twisting or blocking of the dripping stent must be avoided. The child was place on the bed cradle and immobilized with arm or leg joints restraints . Mother learned how to care the catheter . Evaluation indicators should be recorded after surgery through accurate observations.for 7 days and each 3 hrs

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Marzieh Fatemian (BS in nursing)

Street address

Mofid Children's Hospital , Mirdamad ST, Shariati AVE

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research Shahid Beheshti
University Medical Sciences

Full name of responsible person

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Street address

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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

Vice chancellor for Research Shahid Beheshti University
Medical Sciences

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**

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Full name of responsible person

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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