

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

A comparative study of The new technique Meatal mobilization with glenoplasty and conventional MAGPI in distal hypospadias repair

Protocol summary

Summary

A comparative study of The new technique Meatal mobilization with glenoplasty and conventional MAGPI in distal hypospadias repair Hypospadiasis- dislocation of meatus in ventral aspect of Penis- is one of the most common anomalies in pediatric urologic disease. The most popular surgical therapy in Distal Hypospadiasis is MAGPI method. In classic MAGPI, especially in cases that meatus has not enough mobilization, curvature deformity due to glans retraction, is the worse consequence. In this study a new method will be introduced which the urethra is released and obtaining the enough length, it will be sutured to the tip of glans. Its results will be compared with classic MAGPI method. This is a randomized clinical trial study on 88 patients with distal hypospadias who have no chordee and have not done previous repair surgery at all. The study will be performed on 2 randomized groups, first on 66 patients whom will be operated by new method and the second group includes 22 patients for classic MAGPI method. The study will carry out as single blind study, meaning that the referees have no knowledge about the groups. Patients will be visited in one week, three months and six months after surgery by two urologist referees, to evaluate the cosmetic outcome, meatus retraction and meatal stenosis. Data will be processed by 16.0 version of SPSS software and in case of better results, this innovated method shall be introduced as the superior method in treatment of distal hypospadias.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111238173N1**

Registration date: **2012-06-28, 1391/04/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-28, 1391/04/08

Registrant information

Name

Babak Kazemzadeh Azad

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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dr.b.kazemzadeh@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of The new technique Meatal mobilization with glenoplasty and conventional MAGPI in distal hypospadias repair

Public title

The New Modified MAGPI In Hypospadiasis Repair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with distal hypospadias including glandular, coronal and subcoronal, referred to the office or clinic and undergone MAGPI surgery
Exclusion criteria: Patients with the history of previous operation and patients with chordee

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 88

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, Kermanshah university of medical sciences

Street address

Beheshti Blv. second building, research and technology department

City

Kermanshah

Postal code

Approval date

2012-05-06, 1391/02/17

Ethics committee reference number

1261

Health conditions studied

1

Description of health condition studied

Hypospadias

ICD-10 code

Q54.0

ICD-10 code description

Hypospadias, balanic

Primary outcomes

1

Description

cosmetic

Timepoint

1 week, 3 months and 6 months after surgery

Method of measurement

cone shape glans- central meatus- slit like meatus

2

Description

duration

Timepoint

from the first incision to the last dressing

Method of measurement

minute

Secondary outcomes

1

Description

complications

Timepoint

1 week, 3 months and 6 months after repair

Method of measurement

Meatal stenosis(inability to pass a 6 or 8 french catheter)- Meatal Retraction

2

Description

Urinary Pattern

Timepoint

1 week, 3 months and 6 months after repair

Method of measurement

appropriate diameter, force and angle of micturition due to referees ideas

Intervention groups

1

Description

In the Control group the operation will be done as traditional MAGPI method (without releasing the urethra)

Category

Treatment - Surgery

2

Description

In the Intervention group, a wedge like incision is done, distal to the meatus up to the tip of Glans; then according to the size of Glans, Urethra will be released and sutured to the tip of Glans in dorsal, lateral and medial side. the rest of the operation is done by routine Glanoplasty

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital, Kermanshah

Full name of responsible person

Dr. Mahmoodreza Moradi

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

Street address

Second building of medical university, Beheshti Blv. ,
Vice chancellor for research and technology

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of 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

University of medical sciences

Full name of responsible person

Dr. Mahmoodreza Moradi

Position

associated professor and Pediatric Urologist

Other areas of specialty/work

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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