# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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
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Iran (Islamic Republic of)
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**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 hypospadiasis including glandular, cronal and subcronal ,refered to the office or clinic and unthergone 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**
Hypospadiasis
**ICD-10 code**
Q54.0
**ICD-10 code description**
Hypospadias, balanic

## Primary outcomes

**1**

**Description**
cosmetic
**Timepoint**
1week,3 months and 6 monthe 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 ang angel of micturation due to referees ideas

## Intervention groups

**1**

**Description**
In the Control group the operation will be done as traditional MAGPI method (whiout 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 routin Glenoplasty
**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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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resident of Urology

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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*