

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Assessment of outcomes in distal hypospadias repair by Snodgrass method with and without Urethral plate incision

#### Protocol summary

##### Study aim

Assessment of outcomes in distal hypospadias repair by Snodgrass method with and without Urethral plate incision

##### Design

The study is a randomized, community-based, and pragmatic clinical trial consisting of 60 patients in 2 parallel groups with double-blind design

##### Settings and conduct

This study is a randomized clinical trial, double-blind at a time period from 2021 to 2022. The subjects of the study included all patients with hypospadias and superficial chordee referred to Tabriz Children's Hospital which was treated as primary and non-consecutive. After entering the study and obtaining consent, for all patients (control and intervention group) at the moment of entering the study, according to the hypospadias, diagnostic and therapeutic measures are performed according to the physician's decision-making.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All hypospadias patients. Exclusion criteria: Dissatisfaction of parents Patient who can't be followed up after surgery for complications History of circumcision History any kind of penile surgery

##### Intervention groups

Intervention group: Hypospadias repair with Urethral plate incision, Control group: Hypospadias repair without Urethral plate incision

##### Main outcome variables

Incidence of urethrocutaneous fistula, Strictures

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200608047702N2**

Registration date: **2022-02-02, 1400/11/13**

Registration timing: **prospective**

Last update: **2022-02-02, 1400/11/13**

Update count: **0**

##### Registration date

2022-02-02, 1400/11/13

##### Registrant information

###### Name

Reza Ramezani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 2321 0333

###### Email address

dr.ramezanireza70@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-09, 1400/11/20

##### Expected recruitment end date

2022-08-21, 1401/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment of outcomes in distal hypospadias repair by Snodgrass method with and without Urethral plate incision

##### Public title

Hypospadias repair by Snodgrass method

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

All hypospadias patients

**Exclusion criteria:**

Dissatisfaction of parents Patient who can't be followed up after surgery for complications History of circumcision History any kind of surgery

**Age**

From **6 months** old to **6 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The sample size was 60 participants (30 people in each group). The block randomization method was developed by an epidemiologist collaborator using version 13 of Stata software. To conceal the random allocation process, 60 treatment cards were written in sequential order, then the cards were placed in sealed envelopes. On each envelope, a random code was written with no sequences that only the methodologist was aware of the code. When the physician announced a patient's eligibility, the methodologist provided the envelope.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The person who evaluated the final outcomes was unaware of the random allocation process and the type of treatment performed. Data were analyzed by a statistical expert who was separated from the study process and unaware of all the processes performed

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Tabriz Medical School

**Street address**

International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Approval date**

2021-07-12, 1400/04/21

**Ethics committee reference number**

IR.TBZMED.REC.1400.361

**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**

incidence of urethrocutaneous fistula

**Timepoint**

daily from the third day after surgery

**Method of measurement**

Physical examination

2

**Description**

Strictures

**Timepoint**

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

**Method of measurement**

Physical examination

**Secondary outcomes**

1

**Description**

Edima and bleeding in surgical site

**Timepoint**

After surgery,daily for 7 days

**Method of measurement**

Observation and follow up

**Intervention groups**

1

**Description**

Intervention group: Hypospadias repair with Urethral plate. In this method, making a longitudinal incision on the urethral plate (UP) with tubularization to make a neourethra incision and using protective dartus flap to

cover the neourethra

**Category**

Treatment - Surgery

**2**

**Description**

Control group: Hypospadias repair without Urethral plate, In this method, Tubularization of the urethral plate is performed without a dorsal mid-line relaxing incision.

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Tabriz Children's Hospital

**Full name of responsible person**

Dr. Fahimeh Kazemi Rashed, Pediatric Urology Subspecialist

**Street address**

No.22, Sheshgelan St., Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 914 117 0855

**Email**

Kazemirashedf@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

mohammad samiee

**Street address**

Golgasht Street. Research and Technology, University of Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 914 117 0855

**Email**

hajebrahimis@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Behzad lotfi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

**Street address**

No.11, Urology Ward, Imam Reza Hospital, Golgasht St., Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

0413347054

**Email**

blotfi@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Fahimeh Kazemi Rashed

**Position**

Associate professor of urology

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

**Street address**

Urology ward, Emam Reza hospital, Golgasht ave.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 3334 7054

**Email**

kazemirashedf@tbzmed.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Reza Mehdi pour

**Position**

Urology Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

**Street address**Urology Ward, Imam Reza Hospital, Golgasht  
St., Tabriz, Iran**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Phone**

+98 41 3334 7054

**Email**

shaghayegh.ghasemi1400@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**Undecided - It is not yet known if there will be a plan to  
make this available**Data Dictionary**Undecided - It is not yet known if there will be a plan to  
make this available**Title and more details about the data/document**

A portion of the data that represents the final outcome

**When the data will become available and for how long**

Access will be 6 months after the results are printed.

**To whom data/document is available**

Urologic specialists in coordination with the presenter

**Under which criteria data/document could be used**The use of data to improve patients' treatment processes  
is safe**From where data/document is obtainable**The person responsible for updating study information dr  
Reza Mehdipur  
Email:shaghayegh.ghasemi1400@gmail.com**What processes are involved for a request to access data/document**Requesting data and study documents will be done by  
correspondence with the person responsible for updating  
the study information**Comments**