

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparison of the results of distal hypospadias surgery using ventral and dorsal dart flaps

#### Protocol summary

##### Study aim

Comparison of the results of distal hypospadias surgery using ventral and dorsal dart flaps

##### Design

The study is a randomized 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

In the intervention group, the ventral dartos flap is used to cover the urethra in the hypospadias surgery. In the control group, the dorsal dartos flap is used to cover the urethra in the hypospadias surgery.

##### Main outcome variables

Incidence of urethrocutaneous fistula, Strictures

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220218054055N1**

Registration date: **2022-10-29, 1401/08/07**

Registration timing: **prospective**

Last update: **2022-10-29, 1401/08/07**

Update count: **0**

##### Registration date

2022-10-29, 1401/08/07

##### Registrant information

###### Name

Behzad Lotfi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3335 7328

###### Email address

lotfib@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-22, 1401/09/01

##### Expected recruitment end date

2023-06-20, 1402/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the results of distal hypospadias surgery using ventral and dorsal dart flaps

##### Public title

distal hypospadias surgery procedures

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

All hypochondriacs patients Age between 6 months and 5

years

**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 **5 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, On 60 cards, the sequence of the surgical procedure was written in 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 patient's parents and the person who evaluated the final outcomes were 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**

2022-08-29, 1401/06/07

**Ethics committee reference number**

IR.TBZMED.REC.1401.500

**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**

Glans and penis size

**Timepoint**

1week, 3 months and 6 months after surgery

**Method of measurement**

HOSE (Hypospadias Objective Scoring Evaluation) check list

**Secondary outcomes**

1

**Description**

complications

**Timepoint**

1 week, 3 months and 6 months after repair

**Method of measurement**

Evaluation of urethrocuteaneous fistula, stricture, disease recurrence

**Intervention groups**

1

**Description**

Intervention group: hypospadias surgery will be operated by the Tubularized incised plate (TIP) technique, and ventral dartos flap will be used to cover the urethra.

**Category**

Treatment - Surgery

2

**Description**

Control group: hypospadias surgery will be operated by

the Tubularized incised plate (TIP) technique, and dorsal dartus flap will be used to cover the urethra.

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mardani Azar Children's Hospital

**Full name of responsible person**

Behzad Lotfi

**Street address**

Khavaran shahrak

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

513377505

**Phone**

+98 41 3336 1018

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blotfi@gmail.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

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Tabriz

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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**

Javad Aliasgarzadeh khiavi

**Position**

Urology Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

**Street address**

Urology Ward, Imam Reza Hospital, Golgasht St., Tabriz, Iran

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Tabriz

**Province**

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j.aliasgarzadeh@yahoo.com

**Person responsible for scientific 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

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Urology ward, Emam Reza Hospital, Golgasht ave.

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## Person responsible for updating data

### 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**

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**Province**

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**Postal code**

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**Phone**

0413347054

**Email**

blotfi@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**

Part of the data on the outcome of hypospadias surgery methods is for sharing

**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**

Urological 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 is Behzad Lotfi Email: lotfib@tbzmed.ac.ir

**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**