Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)
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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 urethrocutaneous fistula, stricture, disease recurrence

Intervention groups

1

Description

Intervention group: hypospadias surgery will be operated by the Tubularized incised plate (TIP) technique, and ventral dartus 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

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513377505

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiee

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Golgasht Street. Research and Technology, University of Tabriz

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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

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

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

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Person responsible for scientific inquiries

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Position

Associate professor

Latest degree

Specialist

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Person responsible for updating data

Contact

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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