Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 41 2321 0333

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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

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No.22, Sheshgelan St.,Tabriz, Iran

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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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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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Fahimeh Kazemi Rashed

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
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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
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