

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigation of the outcome of full thickness thigh graft for the correction of concealed penis in boys aged 7 to 14 years

Protocol summary

Study aim

Choosing the right surgical method to improve the appearance and function of the penis and increase the health of the genital area in children with an indented penis

Design

Clinical trial with control group, with parallel groups, randomized, phase 2 on 60 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Patients are examined at the specialized clinic of pediatric surgery and after confirming the diagnosis and selecting patients with indications for surgery, the study is fully explained to the parents and they are included in the study if they wish. Patients are randomly assigned to the intervention and control groups. Then they are admitted to the operating room of Isfahan teaching hospitals and undergo the described surgery. At six months old, they are examined and interviewed in a specialized pediatric clinic. According to the type of intervention and surgical treatment, blinding is not possible.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with concealed penis over 7 years old Exclusion criteria: Reluctance to continue participating in the plan. Concomitant coagulation disorder

Intervention groups

In this study, to correct the hidden penis in children with the above diagnosis, from the autologous full-thickness skin interposition graft from the thigh area and embedding it in the trunk of the penis after releasing Dartus adhesions, the performance and outcomes investigated in the study were monitored in the post-operative examinations. and are checked. The control group consists of children with hidden penis who did not undergo the above surgery at the mentioned age for any reason.

Main outcome variables

Improving the appearance and function of the penis and increasing the hygiene of the genital area in children with hidden penis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230513058160N1**

Registration date: **2023-05-27, 1402/03/06**

Registration timing: **retrospective**

Last update: **2023-05-27, 1402/03/06**

Update count: **0**

Registration date

2023-05-27, 1402/03/06

Registrant information

Name

Davud Moznebi Esfahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3236 7106

Email address

dr.moznebi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

2021-10-23, 1400/08/01

Actual recruitment end date

2022-11-21, 1401/08/30
Trial completion date
2023-05-20, 1402/02/30

Scientific title
Investigation of the outcome of full thickness thigh graft for the correction of concealed penis in boys aged 7 to 14 years

Public title
The result of full-thickness femoral graft for the correction of concealed penis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children with concealed penis over 7 years old
Exclusion criteria:
Reluctance to continue participating in the plan
Concomitant coagulation disorder

Age
From **7 years** old to **14 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**
Actual sample size reached: **60**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
No.8 Pour gol afshan Ave Lonban Blv
City
Esfahan
Province
Isfahan
Postal code

8184664131
Approval date
2023-05-09, 1402/02/19
Ethics committee reference number
IR.MUI.MED.REC.1402.073

Health conditions studied

1

Description of health condition studied

Concealed penis

ICD-10 code

N48

ICD-10 code description

Other disorders of penis

Primary outcomes

1

Description

Phallus morphology

Timepoint

Pre-operative visit and visit one week and 1,3, 6 months after the operation

Method of measurement

The morphology of the penis is recorded by measuring the length of the penis from its root with finger pressure on both sides of the penis before surgery and in subsequent visits.

Secondary outcomes

1

Description

Phallus function

Timepoint

Before the operation and the interval of a week and 1, 3, 6 months after the operation

Method of measurement

Relevant training is given to the parents to check and record the function of the penis during discharge, which is an assessment of the improvement of the child's urinary erection during urination.

2

Description

Genital hygiene

Timepoint

Before the operation and the interval of a week and 1, 3, 6 months after the operation

Method of measurement

Evaluation of the reduction of subalternal debris after surgery is done by parents at home and by clinical examination by pediatric surgery specialist in post-operative visits.

Intervention groups

1

Description

Intervention group: After admitting the patient to perform the operation, he is placed under general anesthesia and placed in the low lithotomy position. After prep and drape, the genital area and lower limbs are placed in the field. A median longitudinal incision is made on the ventral penile skin from the phimotic ring to the penoscrotum junction. For traction with Prolene 5.0, a permanent suture is placed at a distance of 5 mm from the edge of the glans and remains until the end of the operation. A peripheral cut is created according to the initial opening. Degloving is performed by dissection of all the dartos fascia of the penis and fibrous tissues from the fascia of the pelvis. Then, after tying a tourniquet at the base of the penis and injecting normal saline, the amount of cord is checked. If the severity of the cord is more than 10 degrees, the cord is corrected by Dorsal Plication with 0-5 Prolen thread using the Nezbit method. The subcutaneous tissue of the junction of the penoscrotum is dissected ventrally at the 6 o'clock position. This simplifies the dissection of the fat tissue of the genital area from the back to the pubic ligaments at 12 o'clock. Then, a full thickness graft with a length of 1.5 times the defect and a width of 1 cm is removed from the non-dominant thigh and defatted. It is useful to use the inguinal skin because it is hairless and next to the penis, and the resulting scar is easily hidden under clothing. Then the graft is transferred to the operation site and fixed at 12, 3, and 9 o'clock, and at 6 o'clock the genital area of the graft is repaired in the form of a ring. 0-4 is sewn. Urethral catheter is inserted based on the age of the patient. Antibiotics are started during induction of anesthesia and are maintained for 3 to 5 days. It ends. After 48 hours, the dressing is removed and the color of the graft is checked

Category

Treatment - Surgery

2

Description

Control group: After admitting the patient for the operation, he is placed under general anesthesia and placed in the supine position. After preparation and drape of the genital area, a longitudinal incision is made on the skin of the abdominal penis from the phimotic ring to the junction of the penoscrotum. is created For traction with Prolene 5.0, a permanent suture is placed at a distance of 5 mm from the edge of the glans and remains until the end of the operation. A peripheral cut is created according to the initial opening. Degloving is performed by dissection of all the dartos fascia of the penis and fibrous tissues of the pelvic fascia. The subcutaneous tissue of the junction of the penoscrotum is dissected ventrally at the 6 o'clock position. This simplifies the dissection of the genital fat tissue from the back to the pubic ligaments at 12 o'clock. The urethral catheter is inserted based on the patient's age.

Antibiotics are started during the induction of anesthesia and are maintained for 3 to 5 days. After 48 hours, the dressing is removed. In this surgical method, no graft is used and only adhesions and fibrous tissue are released.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

Mehrdad Hosseinpour

Street address

Ebn Sina Ave, Sonbolestan Street

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Email

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Web page address

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2

Recruitment center

Name of recruitment center

Imam Hossein Children's Hospital

Full name of responsible person

Mehrdad Hosseinpour

Street address

Isfahan, Imam Khomeini St., before Esteghlal Square, Imam Hossein Children's Educational Therapy Center

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Web page address

<https://ehuch.mui.ac.ir/fa>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mozghan Mortazavi

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Hazar Jarib St., Isfahan University of Medical Sciences
and Health Services, School of Medicine

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8174673461

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research@mui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Davud Moznebi Esfahani

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

No - There is not a plan to make this available

Analytic Code

Not applicable

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

After de-identifying individual information, individual complications or unintended consequences are shared

When the data will become available and for how long

Access starts 1 year after results are published

To whom data/document is available

Access for researchers in the field of pediatric surgery, urology and plastic surgery

Under which criteria data/document could be used

The data can be used for reference in future researches

From where data/document is obtainable

The request will be made by email with the specialist assistant of Dr. Davud Moznabi and after providing the documents of the research project and the data used in the research by the applicant and after verifying the identity of the applicant. dr.moznebi@yahoo.com

What processes are involved for a request to access data/document

Sending an email request and scientific and personal specifications, resume and documentary information can be requested for the research project The data will be made available as soon as possible after the confirmation of the individual inquiry and research plan

Comments