

# 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

##### City

Esfahan

##### Province

Isfahan

##### Postal code

81486-53141

##### Phone

+98 31 3445 5051

##### Email

dr.moznebi@yahoo.com

##### Web page address

<https://amin.mui.ac.ir>

### 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

##### City

Esfahan

##### Province

Isfahan

##### Postal code

81951-63381

##### Phone

+98 31 3386 6266

##### Email

dr.moznebi@yahoo.com

##### 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

**Street address**

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

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3668 8138

**Email**

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

**Street address**

No. 8 Pour Gol afshan Ave, Lonban Blvd, Esfahan

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8184664131

**Phone**

+98 31 3236 7106

**Fax**

**Email**

dr.moznebi@yahoo.com

**Person responsible for scientific  
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

**Street address**

No. 8 Pour Gol afshan Ave, Lonban Blvd, Esfahan

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8184664131

**Phone**

+98 31 3236 7106

**Fax**

**Email**

dr.moznebi@yahoo.com

**Person responsible for updating data**

**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

**Street address**

No. 8 Pour Gol afshan Ave, Lonban Blvd, Esfahan

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8184664131

**Phone**

+98 31 3236 7106

**Fax**

**Email**

dr.moznebi@yahoo.com

**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**