

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of testosterone injection on the results of hypospadias surgery

Protocol summary

Study aim

The effect of testosterone injection on the results of hypospadias surgery

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 2022 to 2023. The subjects of the study included all patients with hypospadias 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 hypochondriacs patients aged 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 of any kind of surgery

Intervention groups

Intervention group: The children will receive 2 ng/kg testosterone enanthate two weeks before surgery. Control group: The control group will not receive any preoperative treatment.

Main outcome variables

Glans and penis size, Incidence of urethrocutaneous fistula, Strictures

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200608047702N4**

Registration date: **2022-07-13, 1401/04/22**

Registration timing: **prospective**

Last update: **2022-07-13, 1401/04/22**

Update count: **0**

Registration date

2022-07-13, 1401/04/22

Registrant information

Name

Reza Ramezani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 2321 0333

Email address

dr.ramezanireza70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of testosterone injection on the results of hypospadias surgery

Public title

Testosterone injection in hypospadias surgery

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

- Care provider
- Data analyser

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

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

2022-06-15, 1401/03/25

Ethics committee reference number

IR.TBZMED.REC.1401.257

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

cone shape glans- central meatus- slit like meatus

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: Repair of hypospadias will be done 2 weeks after intramuscular injection of a single dose of testosterone 2 mg/kg by Aburihan company. Post-operative complications include: urethrocuteaneous fistulas, stricture, and the average length and circumference of the penis will be measured after the operation.

Category

Treatment - Surgery

2

Description

Control group: The control group will not receive any

treatment before the hypospadias repair operation.
Category
Treatment - Drugs

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
Street address
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
Street address
Golgashat Street. Research and Technology, University
of 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
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 scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Danial Farhadi

Position

Urology Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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 testosterone injection in hypospadias surgery 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
danial farhadi Email: danifarhadi20@gmail.com

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

En Requesting data and study documents will be done by correspondence with the person responsible for updating the study information

Comments