Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of the complications of transinguinal orchiopexy and standard orchiopexy of palpable testicles in children under two years old referred to Tabriz Children's Hospital

Protocol summary

Study aim
Evaluation of complications in both trans-inguinal orchiopexy and standard orchiopexy in children under two years old

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 100 patients. The random number table was used for randomization.

Settings and conduct
Two surgical procedures are performed in Tabriz Children's Hospital on the undescended testicles of children aged six to twenty-four months. Methods include trans-inguinal orchiopexy and conventional method as control. Patients are unaware of the type of surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Palpable undescended testis Exclusion criteria: Unpalpable undescended testis Intra-abdominal testis No evidence of testis in pre-operative imaging Severely atrophic testis Bilateral undescended testis The presence of other anomalies along with the undescended testis Associated Genetic Disorders

Intervention groups
1: case group: Trans-inguinal orchiopexy 2: control group: conventional orchiopexy

Main outcome variables
Testicular volume, Scrotal appearance, Testicular ischemia, Duration of surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150124020767N4**
Registration date: **2020-05-28, 1399/03/08**
Registration timing: **registered_while_recruiting**
Last update: **2020-05-28, 1399/03/08**
Update count: **0**

Registration date
2020-05-28, 1399/03/08

Registrant information
Name
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Name of organization / entity
tabriz medical sciences university
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2020-09-21, 1399/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the complications of transinguinal orchiopexy and standard orchiopexy of palpable testicles in children under two years old referred to Tabriz Children's Hospital

Public title
Comparison of the complications of of transinguinal

orchiopexy and standard orchiopexy of palpable testicles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Palpable undescended testis

Exclusion criteria:

Unpalpable undescended testis Intra-abdominal testis No evidence of testis in pre-operative imaging Severely atrophic testis Bilateral undescended testis The presence of other anomalies along with the undescended testis Associated Genetic Disorders

Age

From **6 months** old to **10 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, Individual, Using a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double-blinded. Patients after obtaining inclusion criteria to enter the study and obtain consent, according to the table of random numbers, will be divided into two groups. They will not interfere in determining the type of treatment and will not know the type of treatment before the treatment process. The analyzer will not be aware of the type of treatment (because it receives the data as a spss file in two separate groups, one and two).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz children"s Hospital, Sheshglan St.

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Approval date

2020-05-03, 1399/02/14

Ethics committee reference number

IR.TBZMED.REC.1399.094

Health conditions studied

1

Description of health condition studied

Undescended testis

ICD-10 code

Q53.1

ICD-10 code description

Undescended testicle, unilateral

Primary outcomes

1

Description

Complications of orchiopexy

Timepoint

One week - one month and three months after surgery

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Testicular volume

Timepoint

Before surgery and three months after surgery

Method of measurement

Ultrasonography

2

Description

Scrotal appearance

Timepoint

One week - one month and three months after surgery

Method of measurement

Inspection. Three groups without skin retraction - minimal retraction - severe scrotal retraction

3

Description

Tissue ischemia

Timepoint

In duration of surgery

Method of measurement

Inspection-Ischemic testicular discoloration

4

Description
Duration of surgery
Timepoint
After surgery
Method of measurement
The watch (time in minute)

Intervention groups

1

Description
Intervention group: Trans-inguinal orchiopexy. In this group, first by inguinal incision, the skin and the inguinal canal are opened in the Langer's lines. The vaginalis process is then separated and the necessary components, including the vas deferen, blood vessels, and spermatic cord, are preserved. The vaginalis process is repaired and the patient's hernia is corrected. Gubrenaculum is then discontinued. Retroperitoneal dissection is performed to release the cord so that the testicle reaches the scrotum and enough spermatic vessels length are formed. A tunnel is created along the canal to the scrotum, and the skin of the scrotum is returned to the inguinal incision with a blunt-skin clamp. The tonica vaginalis around the testicle is fixed in two places with absorbable vicryl sutures, and then the dartus layer is repaired, and then the external iliac apineurosis and skin is repaired . Patient is examined for skin tension and the time of surgery and complications during surgery (including ischemia, bleeding, hematoma and the impossibility of creating sufficient length in the spermatic cord). The patient will be discharged on the evening of the day of surgery if the clinical condition is appropriate. Follow-up examinations will be performed in the following week and one month after surgery . Three months after the surgery, the appearance will be checked and the ultrasound will be done in terms of the size and dimensions of the testicles and their location (problems caused by ischemia and atrophy).
Category
Treatment - Surgery

2

Description
Control group: In patients referred to this group, first the skin and the inguinal canal are opened in the longitudinal lines by inguinal incision. The vaginalis process is then removed and the necessary components, including thevas deferens, blood vessels, and spermatic lymphatic vessels, are preserved. The vaginalis process is repaired and the patient's hernia is corrected. The gubernaculum is then cut. Retroperitoneal dissection is performed to release the cord so that the testicle reaches the scrotum and enough spermatic vessels are formed. A tunnel is created along the canal to the scrotum, cut through the skin incision in the scrotal area, and a scalpel is inserted into the dartus muscle through the scrotal wound. With the clamp inserted into the inguinal cavity, the testicle is pulled into the scrotal wound. The testis is placed inside the dartus muscle sac. The tonic vaginalis around the testicle is fixed in two places with absorbable vicryl sutures, and then the dartus is repaired, and then the external iliac aponeurosis and skin is repaired .Patient is examined for skin tension and the time of surgery and complications during surgery (including ischemia, bleeding, hematoma and the impossibility of creating sufficient length in the spermatic cord). The patient will be discharged on the evening of the day of surgery if the clinical condition is appropriate. Follow-up examinations will be performed in the following week and one month after surgery . Three months after the surgery, the appearance will be checked and the ultrasound will be done in terms of the size and dimensions of the testicles and their location (problems caused by ischemia and atrophy).
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Children's Hospital
Full name of responsible person
Masoud Jamshidi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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5136735886
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Email

Research-vice@tbzmed.ac.ir

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

Masoud Jamshidi

Position

Assissted professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Position

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Phone

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Email

masoudjamshidi@gmail.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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after unidentifiable people

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

N/A

From where data/document is obtainable

Email

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

As soon as possible

Comments