

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of complications after surgery in undescended testicle orchiopexy with an inguinal incision with inguinal and scrotal incision methods.

Protocol summary

Study aim

Comparison of complications in two methods of transinguinal orchiopexy and standard method in palpable testicles of children under two years old

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, on 100 patients. A table of random numbers was used for randomization.

Settings and conduct

Method: Patients with non-palpable testicle who referred to the Mardani Azari children's hospital clinic in tabriz town from March 1402 to March 1402 are included in the study. Inclusion and exclusion criteria are applied and informed consent is obtained from parents. Then the intervention is done in two control and case groups. In the control group, after the initial surgical procedures, a tunnel is created in the canal to the scrotum, and the testicle is placed inside the dartos muscle pouch with skin incision. In the case group, the scrotum bag is pulled up to the wound and the testicle is fixed in the sub-dartuspouch.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with unilateral palpable undescended testicles Exclusion criteria: Non- palpable testis intra-abdominal testis Absence of the testicles in the evaluation before surgery Severely atrophic testis Bilateral undescended testis The existence of other anomalies associated genetic disorder.

Intervention groups

Intervention group: Trans-inguinal orchiopexy
Comparison group: conventional orchiopexy

Main outcome variables

Outcomes: During surgery: Scrotal appearance after surgery and skin traction, surgery time, and complication during surgery(ischemia, hemorrhage, hematoma, inability to create inadequate spermatic cord length) One week and one month after surgery: Scrotal appearance

and complication(include infection, dehiscence, edema, hematoma and ecchymosis. Three months after surgery: appearance ultra-sonographic finding about volume and dimension of testicle.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150124020767N5**

Registration date: **2024-03-02, 1402/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2024-03-02, 1402/12/12**

Update count: **0**

Registration date

2024-03-02, 1402/12/12

Registrant information

Name

masoud jamshidi

Name of organization / entity

tabriz medical sciences university

Country

Iran (Islamic Republic of)

Phone

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Email address

jamshidim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-29, 1402/12/10

Expected recruitment end date

2024-05-20, 1403/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of complications after surgery in undescended testicle orchiopexy with an inguinal incision with inguinal and scrotal incision methods.

Public title

orchiopexy in undescended testicle.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with unilateral undescended testicles who have palpable testicles in the inguinal canal.

Exclusion criteria:

Non-palpable testis Intra-abdominal testis Absence of testis in preoperative imaging Severely atrophic testis Bilateral undescended testes Associated anomalies with undescended testis Associated genetic anomalies

Age

From **6 months** old to **24 months** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization :Simple, Tools used in randomization:based on the random.org online site. Patient will be randomly assigned to two intervention and comparison groups after diagnosis and evaluation of inclusion and exclusions criteria.allocation to two groups will be done through the random.org online site without changing the sequence.In this site we enter the "numbers " section ten the "sequence generator" . As the total sample for this study is 100 psubjects the smallest value will be 1 and the largest us 100. The column should be 2 to get two series of random numbers. Then then we click on "get sequence" . The resulting sequence will be two columns of numbers that each number shows the number of entering patient and each column shows each study group that is intervention or control. The resulting numbers in each group will be entered the Excel to make them from smallest to largest. Concealment will not be done due to impossibility.

Blinding (investigator's opinion)

Not blinded

Blinding description**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 University of Medical Sciences

Street address

Mardani Azari Children hospital, Tabriz, east Azerbaijan

City

Tabriz

Province

East Azarbaijan

Postal code

5166/15731

Approval date

2023-12-18, 1402/09/27

Ethics committee reference number

IR.TBZMED.REC.1402.679

Health conditions studied**1****Description of health condition studied**

Undescended testicle, unilateral

ICD-10 code

Q53.1

ICD-10 code description

Undescended testicle, unilateral

Primary outcomes**1****Description**

complication rate of undescended testis surgery

Timepoint

One week and one month and three months after surgery

Method of measurement

Observation and ultra-sonography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group:Patients who refer to the children's

hospital clinic from the February 2024 until the end of 19th May 2024 are examined first. If there is no testicle in the scrotum unilaterally and the same testicle is touched in the inguinal canal, they are included in the study. Patients with age below six months and age above two years are excluded from the study. For all patients, ultrasound is performed and the findings including the location of the testicles and the dimensions and volume of both testicles are recorded. Patients are admitted and consent to study is obtained from the parents. Patients are examined by attending physician and anesthesiologist. Initial tests include blood cell count is obtained. Patients with concomitant diseases and chronic disorders are excluded from the study. According to the order of entry into the study, patients are divided and odd numbers are included in the intervention group and even numbers are included in the comparison group. Parents are unaware of the groups. For both groups of interventions, the same general anesthesia is performed according to the anesthesia references. In the patients of the intervention group, the inguinal incision is first opened in the Langer lines of the inguinal canal area. Then the process vaginalis is removed and the necessary parts, including the vas deferens and spermatic blood and lymphatic vessels, are separated from it. The vaginal process is repaired and the patient's hernia is repaired. Then the gubernaculum is cut and hemostasis is done. The vas deferens and the spermatic vessels and the related testicle are preserved. Retro-peritoneum dissection is performed to free the cord so that the testicle reaches the scrotum and sufficient length of the spermatic vessels is created. The path of the testicle to the scrotum is opened by the surgeon's finger. Then, without cutting the scrotum, the skin of the scrotum is pulled up to the inguinal incision site by the surgeon's finger guide with a blunt tool. A pouch is formed between the skin of the scrotum and the dartos fascia. The testicle is placed inside poach and fixed to the skin of the scrotum with an absorbable suture. Then the skin along with the testicle is pulled down to the natural place. Then, the oblique external aponeurosis and subcutaneous tissue are repaired.

Category

Treatment - Surgery

2

Description

Control group: Patients who refer to the children's hospital clinic from the January 2024 until the end of 19th May 2024 are examined first. If there is no testicle in the scrotum unilaterally and the same testicle is touched in the inguinal canal, they are included in the study. Patients with age below six months and age above two years are excluded from the study. For all patients, ultrasound is performed and the findings including the location of the testicles and the dimensions and volume of both testicles are recorded. Patients are admitted and consent to study is obtained from the parents. Patients are examined by attending physician and anesthesiologist. Initial tests include blood cell count is obtained. Patients with concomitant diseases and chronic disorders are excluded from the study. According to the

order of entry into the study, patients are divided and odd numbers are included in the case group and even numbers are included in the control group. Parents are unaware of the groups. For both groups of interventions, the same general anesthesia is performed according to the anesthesia references. In the patients of the intervention group, the inguinal incision is first opened in the Langer lines of the inguinal canal area. Then the process vaginalis is removed and the necessary parts, including the vas deferens and spermatic blood and lymphatic vessels, are separated from it. The vaginal process is repaired and the patient's hernia is repaired. Then the gubernaculum is cut and hemostasis is done. The vas deferens and the spermatic vessels and the related testicle are preserved. Retro-peritoneum dissection is performed to free the cord so that the testicle reaches the scrotum and sufficient length of the spermatic vessels is created. A tunnel is created on the path of the canal to the scrotum, and the skin of the scrotum is incised, and a pouch is created with a clamp between dartos fascia and scrotal skin. Then with a clamp inserted into the inguinal canal, the testicle is pulled down into the scrotal pouch. The testicle is placed inside the pouch of the dartos fascia. The tunica vaginalis around the testicle is fixed with vicryl absorbable thread in two places, and then dartos is repaired. Then, the oblique external aponeurosis and subcutaneous tissue are repaired.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahra Mardani Azari Children hospital

Full name of responsible person

Masoud Jamshidi

Street address

Zahra Mardani Azari Children hospital, Mardani Azari street, Khavaran town, Tabriz

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Phone

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Email

masoudjamshidi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz

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masoudjamshidi@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

Masoud Jamshidi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Masoud Jamshidi

Position

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Latest degree

Subspecialist

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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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Individuals can request to receive data and documents at the m.khaaste@gmail.com and the data will be sent after the approval of the university. according to the university guidelines, the data can only be provided to university researchers. There is no limit to data analysis. data must be remain confidential. Any publication of the whole or part of the data requires the permission and approval of the original researcher so that bias does not occur in the data analysis. In case of publication, researcher must cite the owner of the data or article.

From where data/document is obtainable

Email address: m.khaaste@gmail.com or jamshidim@tbzmed.ac.ir Phone number:989127981446

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

After registering the application in the email address, the correspondence with the university will be done to get approval and after receiving the approval, the data will be sent. this process will take about one week.

Comments