

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of inguinal exploration and laparoscopic exploration of nonpalpable undescended testis with cord-like structure on palpation, on requirement to open surgery procedure in patients with undescended testis

Protocol summary

Study aim

Determining the necessity of performing laparoscopic exploration in nonpalpable undescended testis with a cord-like structure on palpation in patients with undescended testis.

Design

In this randomized clinical trial, 40 patients will be randomly divided into intervention and control groups. randomization will be carried out by RAS Software (Random Allocation Software). There will be no blinding in this study.

Settings and conduct

This study will be performed in the surgery ward of Zahra Mardani Azar Children's Hospital, Tabriz, Iran. Patients referring to Zahra Mardani Azari Children's Hospital clinic will be enrolled. There will be no blinding in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: a definitive diagnosis of undescended testis (UDT) by a pediatric surgeon and indication for surgery, minimum age of 12 years, absence of inguinal region anomaly, palpation of cord-like structure in examination by two pediatric surgeons. Exclusion criteria: parents' lack of consent to participate in the study, accompanying anomalies, contraindications for surgery.

Intervention groups

Intervention group: open surgery from the beginning (without the use of laparoscopic exploration). In this group, the inguinal area will be explored in an open form from the beginning, and if the cord elements pass through the inner ring of the inguinal canal into the canal, after the anatomical correction, the surgery will be terminated. Control group: conventional procedure of the priority of laparoscopic exploration over open surgery.

Main outcome variables

evaluating the percentage of patients who need open

surgery after laparoscopic exploration. evaluating the percentage of patients who needed open surgery and underwent open surgery without laparoscopic exploration.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231217060442N1**

Registration date: **2024-02-13, 1402/11/24**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-13, 1402/11/24**

Update count: **0**

Registration date

2024-02-13, 1402/11/24

Registrant information

Name

vahid hamzei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3638 8728

Email address

vahid1hamzei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-05, 1402/10/15

Expected recruitment end date

2024-05-04, 1403/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of inguinal exploration and laparoscopic exploration of nonpalpable undescended testis with cord-like structure on palpation, on requirement to open surgery procedure in patients with undescended testis

Public title
Requirement to open surgery in patients with nonpalpable undescended testis, with cord-like structure on palpation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of undescended testis (UDT) by a pediatric surgeon and indication for surgery Minimum age of 12 years Absence of inguinal region anomaly Palpation of cord-like structure in examination by two pediatric surgeons
Exclusion criteria:
Parents' lack of consent to participate in the study Accompanying anomalies Contraindications for surgery

Age
To **12 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization. After entering the clinic and meeting the inclusion criteria, the patients will receive a random number that is generated by a calculator instantly and is multiplied by the sample size. If the number is odd, the patient will be included in the intervention group, and if the number is even, the patient will be included in the control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, double blinding will be used. Double blind:
1- Patients (participants) will be divided into two groups according to the table of random numbers after meeting the conditions of the study and obtaining consent. The parents of the patients will not be involved in determining the type of treatment. 2- The research physician who provides the intervention will not be

aware of how the groups will be assigned to the intervention and control.

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
Golgashat Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471

Approval date
2023-12-09, 1402/09/18

Ethics committee reference number
IR.TBZMED.REC.1402.660

Health conditions studied

1

Description of health condition studied
nonpalpable undescended testis with cord-like structure on palpation

ICD-10 code
Q53.9

ICD-10 code description
Undescended testicle, unspecified

Primary outcomes

1

Description
The percentage of patients who need open surgery after laparoscopic exploration.

Timepoint
immediately during surgery

Method of measurement
Counting the number of patients who require reoperation despite the initial laparoscopic examination.

2

Description
The percentage of patients who needed open surgery

and underwent open surgery without laparoscopic exploration.

Timepoint

immediately during surgery

Method of measurement

Counting the number of patients who needed open surgery and underwent open surgery without laparoscopic exploration.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients who undergo open surgery from the beginning, despite the standard treatment process with initial. In the intervention group, the inguinal area will be explored in an open form from the beginning, and if the cord elements pass through the inner ring of the inguinal canal into the canal, after the anatomical correction, the surgery will be terminated.

Category

Treatment - Surgery

2

Description

Control group: conventional procedure of concurrent laparoscopic exploration and open surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahra Mardani Azari Hospital

Full name of responsible person

Vahid Hamzeie

Street address

Tabriz University of Medical Sciences, Golgasht Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hamid Tayyebi Khosroshahi

Street address

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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

Saeed Aslanabadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Position

Sub Specialty Resident

Latest degree

Specialist

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

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data related to demographic information, pre-operative findings and post-operative results can be shared after de-identifying individuals.

When the data will become available and for how long

Data will be available starting 6 months after publication

To whom data/document is available

Data will only be available for people working in academic institutions

Under which criteria data/document could be used

Any kind of statistical analysis on the data of this study is allowed if requested by researchers.

From where data/document is obtainable

Researchers can submit their request via e-mail to the responsible author - Dr. Aslan Abadi - at the address below. aslanabadis@tbzmed.ac.ir

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

After sending the requested email and explaining the study that the researcher wants to do, and if approved by the responsible author, the data will be available to her after one week.

Comments