Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the efficacy of one stage laparoscopic abdominal testis orchiopexy in supine position vs novel method of laparoscopic orchiopexy in lateral decubitus position with colon medialization as a randomized clinical trial

Protocol summary

Study aim

Evaluation of the efficacy of one stage laparoscopic abdominal testis orchiopexy in supine position Vs novel method of laparoscopic orchiopexy in lateral decubitus position with colon medialization

Design

A clinical trial with two groups of patients: parallel, therapeutic, simple randomization, single blind (The patients have no information about the surgical procedure and the design). 52 patients referred to Sinai Hospital.

Settings and conduct

This clinical trial will be performed on 52 patients at Sina Hospital. single blind (The patients have no information about the surgical procedure and the design).Patients are divided into two groups of surgery and the quality of treatment results is evaluated. After completing the written consent, they will be placed in one of two groups of (one stage laparoscopic abdominal testis orchiopexy in supine position) or (novel method of laparoscopic orchiopexy in lateral decubitus position with colon medialization).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Untouchable testicles, Which is available in laparoscopy and requires archiopexy. Consent to participate in the study. peeping testis,The testicles are pressed only on the abdomen and in the upper part of the inguinal canal Exclusion criteria: Patients with palpable testicles in the middle of the canal, and scrotum.blind end vessel and vanished testi.Patients over 15 years old.redo patients.Patients splenic fusion or other rare types of abnormalities associated with testicular prolapse (such as Persistent Müllerian Duct Syndrome).Differences in sex development.

Intervention groups

Group1: one stage laparoscopic abdominal testis orchiopexy in supine position. group2: novel method of laparoscopic orchiopexy in lateral decubitus position with colon medialization.

Main outcome variables

The rate of testicular descent - The rate of complete atrophy at the time of follow-up

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200905048625N2**
Registration date: **2022-05-09, 1401/02/19**
Registration timing: **prospective**

Last update: **2022-05-09, 1401/02/19**
Update count: **0**

Registration date

2022-05-09, 1401/02/19

Registrant information

Name

seyed reza hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8560

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-06-10, 1401/03/20
Expected recruitment end date
2023-03-11, 1401/12/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of one stage laparoscopic abdominal testis orchiopexy in supine position vs novel method of laparoscopic orchiopexy in lateral decubitus position with colon medialization as a randomized clinical trial

Public title
One stage laparoscopic abdominal testis orchiopexy in supine position Vs novel method of laparoscopic orchiopexy in lateral decubitus position with colon medialization
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Untouchable testicles, Which is available in laparoscopy and requires archiopexy. Consent to participate in the study Peeping testis,The testicles are pressed only on the abdomen and in the upper part of the inguinal canal
Exclusion criteria:
Patients with palpable testicles in the middle of the canal, and scrotum Blind end vessel and vanished testi Patients over 15 years old Redo patients Patients splenic fusion or other rare types of abnormalities associated with testicular prolapse (such as Persistent Müllerian Duct Syndrome) Differences in sex development
Age
From **12 months** old to **15 years** old
Gender
Male

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
The present study is a single-blind randomized clinical trial. For randomization, the blanced block randomization method is used to generate four blocks. Intervention group A and control group B have been determined.According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the sealdenvelop online site, the generated sequence will be made available to a technician outside the research team.Quadruple blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected and the type of patient group is informed to the research team through a trained technician.The patient is placed in treatment group based on the randomly selected envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients who have agreed to participate in the study undergo surgery, then undergo surgery without knowing the existence of two groups of surgeries.
Placebo
Not used
Assignment
Parallel
Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee for Research in Tehran University of Medical Sciences
Street address
Room 604, Sixth Floor, Tehran medicine University , Central Staff Building, Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2021-10-27, 1400/08/05
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1400.091

Health conditions studied

1

Description of health condition studied
Abdominal testis orchiopexy
ICD-10 code
Q53.11
ICD-10 code description
Abdominal testis, unilateral

Primary outcomes

1

Description

The rate of testicular descent

Timepoint

10 days, 6 weeks and six months after surgery

Method of measurement

Examination of the patient by a physician

Secondary outcomes

1

Description

The rate of complete atrophy at the time of follow-up

Timepoint

10 days, 6 weeks and six months after surgery

Method of measurement

Examination of the patient by a physician

Intervention groups

1

Description

Intervention group: one stage laparoscopic abdominal testis orchiopexy in supine position

Category

Treatment - Surgery

2

Description

Intervention group: novel method of laparoscopic orchiopexy in lateral decubitus position with colon medialization

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Seyed Reza Hosseini

Street address

Urology Research Center, Sina Hospital, Hassan Abad

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1136746911

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Keshavarz Boulevard, Quds Ave., Central University, Sixth Floor

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr Akram Mirzaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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https://URC@tums.ac.ir

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
No - There is not 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
demographic information anonymously
When the data will become available and for how long
one year after publication
To whom data/document is available
Researchers working in academia, physicians, surgeons and hospitals
Under which criteria data/document could be used
Any analysis can be done with the consent of the main researcher
From where data/document is obtainable
Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Reza Hosseini 00982166348560
What processes are involved for a request to access data/document
After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.
Comments
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