

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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

Email address

srhoseini@tums.ac.ir

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

AgeFrom **12 months** old to **15 years** old**Gender**

Male

Phase

N/A

Groups that have been masked

- Participant

Sample sizeTarget 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

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Urology Research Center, Sina Hospital, Hassan Abad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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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

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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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