

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparing of single scrotal incision orchiopexy for children with palpable low-lying undescended testis with traditional inguinal orchiopexy method

Protocol summary

Summary

The aim of present study is to evaluate the results of single scrotal incision orchiopexy and comparing with traditional inguinal orchiopexy method for children with palpable low-lying undescended testis in inguinal canal. In a single center randomized clinical trial study, 60 patients with undescended testis who referred to Children Hospital educational-medical center of Tabriz University of Medical Sciences will allocate in two groups. Inclusion criteria are children with age under 2 years old, unilateral undescended testis, no touch of testes in inguinal canal, and low-lying undescended testis. Exclusion criteria are history of inguinal surgery, history of abdominal surgery, secondary ascending testes, ectopic testes, and ambiguous genitalia. In first group orchiopexy will done with low invasive single scrotal incision technique (n=30) and in second group orchiopexy will done with classic double incision technique (inguinal region & scrotal) (n=30). After surgery patients will followed up for 6 months. Patients will evaluate in term of duration of surgery and wound infection as primary outcome variables and also will evaluate for rate of recurrence, and testicular atrophy as secondary outcome variables.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041020663N2**
Registration date: **2016-05-18, 1395/02/29**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-18, 1395/02/29

Registrant information

Name

Davoud Badebarin

Name of organization / entity

Country

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Email address

badebarind@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University Of Medical Sciences.

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of single scrotal incision orchiopexy for children with palpable low-lying undescended testis with traditional inguinal orchiopexy method

Public title

Comparing of single scrotal incision orchiopexy for children with palpable low-lying undescended testis with traditional inguinal orchiopexy method

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children with age under 2 years old; unilateral undescended testis; no touch of testes in

inguinal canal; low-lying. Exclusion criteria: history of inguinal surgery; history of abdominal surgery; secondary ascending testes; ectopic testes; ambiguous genitalia.

Age

To 2 years old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Tabriz University Of Medical Sciences

Street address

Tabriz University Of Medical Sciences, Daneshgah Street, Tabriz.

City

Tabriz

Postal code**Approval date**

2015-12-07, 1394/09/16

Ethics committee reference number

TBZMED.REC.1394.819

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

Low-lying undescended testis

ICD-10 code

N50.9

ICD-10 code description

Disorder of male genital organs, unspecified

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

Wound infection

Timepoint

one week after surgery

Method of measurement

Clinical examination

2**Description**

Duration of Surgery

Timepoint

After surgery

Method of measurement

Measurement of surgery time

Secondary outcomes**1****Description**

Recurrence of undescended testis

Timepoint

six month after surgery

Method of measurement

Clinical examination

2**Description**

Testicular atrophy

Timepoint

six month after surgery

Method of measurement

Clinical examination

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

In Intervention Group: surgery of undescended testis will be done with single scrotal incision technique.

Category

Treatment - Surgery

2**Description**

In control group: surgery of undescended testis will be done with classical double incision technique (inguinal region and scrotal).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Hospital of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Davoud Badebarin

Street address

Children Hospital, Sheshgelan street, Tabriz.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University Of Medical Sciences.

Full name of responsible person

Dr Hasan Soleimanpour

Street address

Deputy of Research and Technology, Central Building of Number Two, Tabriz University of Medical Sciences, Daneshgah Street, Tabriz.

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tabriz University Of Medical Sciences.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Dr Ebrahim Farhadi

Position

Resident of Surgery Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department Of Surgery, Tabriz University of Medical Sciences.

Full name of responsible person

Dr. Davoud Badebarin

Position

Pediatric Surgery Sub-specialist.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty