

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

A Comparative Study of Surgery results with and without Ligation hernia SAC in Orchiopexy Childrens with Undescended Testis

Protocol summary

Summary

This study was done with aim to Comparative Study of results of the hernia sac ligation surgery in Orchiopexy childrens with undescended testis. This study is a single blind clinical trial. The population will consist of children 1 to 10 years old with undescended testis and without clinical inguinal hernia and undergoing Orchiopexy Referring to Mohammad Kermanshahi hospital during the 2012-2013 . That 16 persons are selected as sample and randomly divided into two(8 members) exprimental and control groups. the hernia sac ligation surgery was performed in the experimental group while the control group do not cause the hernia sac ligation surgery. Then the hematoma and bleeding, hydrocele, wound infection, recurrence, swelling and cord inflammation was recorded and patients for 6 months and for: A week after the operation and one, three and six months after the operation were followed and both groups were compared. Inclusion criteria: children 1 to 10 years old with undescended testis;written consent of the patient or the patient's guardian. Exclusion criteria: clinical inguinal hernia (visible) along with undescended testis;hernia stuck with undescended testis; deterrent hernia along with undescended testis; increased intra-abdominal pressure for any reason (dialysis, etc.) along with undescended testis.

General information

Acronym

A Comparative Study of Surgery results with and without Ligation hernia SAC in Orchiopexy Childrens

IRCT registration information

IRCT registration number: **IRCT2015101214333N42**

Registration date: **2015-10-27, 1394/08/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-27, 1394/08/05

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2013-09-06, 1392/06/15

Expected recruitment end date

2014-09-06, 1393/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study of Surgery results with and without Ligation hernia SAC in Orchiopexy Childrens with Undescended Testis

Public title

A Comparative Study of results of Ligation hernia Surgery SAC in Orchiopexy Childrens with Undescended Testis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children 1 to 10 years old with undescended testis; written consent of the patient or the patient's guardian. Exclusion criteria: clinical inguinal hernia (visible) along with undescended testis; hernia stuck with undescended testis; deterrent hernia along with undescended testis; increased intra-abdominal pressure for any reason (dialysis, etc.) along with undescended testis.

Age

From **1 year** old to **10 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee Ethics, Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2015-10-11, 1394/07/19

Ethics committee reference number

kums.rec.1394.97

Health conditions studied

1

Description of health condition studied

Undescended testicle, bilateral

ICD-10 code

Q53.2

ICD-10 code description

Undescended testicle, bilateral

Primary outcomes

1

Description

hematoma and bleeding

Timepoint

A week after the operation and one, three and six months after the operation

Method of measurement

According to the surgeon examination

2

Description

wound infection

Timepoint

A week after the operation and one, three and six months after the operation

Method of measurement

Based on the clinical symptoms and physician observation

3

Description

Swelling and cord inflammation

Timepoint

A week after the operation and one, three and six months after the operation

Method of measurement

According to the sonography and physician observation

4

Description

Recurrence after operation

Timepoint

A week after the operation and one, three and six months after the operation

Method of measurement

According to the sonography and physician observation

Secondary outcomes

empty

Intervention groups

1

Description

The hernia sac ligation surgery was performed in the experimental group, Then the hematoma and bleeding, hydrocele, wound infection, recurrence, swelling and cord inflammation was recorded and patients for 6 months and for: A week after the operation and one,

three and six months after the operation were followed.

Category

Treatment - Surgery

2

Description

The hernia sac ligation surgery was not performed in the control group, Then the hematoma and bleeding, hydrocele, wound infection, recurrence, swelling and cord inflammation was recorded and patients for 6 months and for: A week after the operation and one, three and six months after the operation were followed.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohammad Kermanshahi Hospital

Full name of responsible person

Dr. Zahra Kashanian

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

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, Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Omid Amanollahi

Position

Pediatrician Surgery

Other areas of specialty/work

Street address

Mohammad Kermanshahi Hospital, Crossroads of Shirkehrshid

City

Kermanshah

Postal code

Phone

+98 833

Fax

Email

oamanollahi@Yahoo.com

Web page address

Person responsible for updating data

Contact

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