

# 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)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### 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; deterring 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**

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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