Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative of two surgical methods in the treatment of pediatrics with hydrocele

Protocol summary

Summary

This study is a single blind, randomized clinical trial. The purpose of this study is comparison between recurrence and complications of two methods of surgery (hydrocelotomy and hydrocelectomy) in the treatment of hydrocele in pediatrics who are candidates for surgical in Imam Reza hospital of Kermanshah. A total of 70 patients are randomly allocated into two groups surgery (hydrocelotomy or hydrocelectomy). Both groups will be followed and compared at first week, third month and sixth month after surgery for recurrence and complications (Damage to spermatic vessels and cord element, bleeding, wound infection, and hematoma).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013013112321N1**
Registration date: **2013-09-22, 1392/06/31**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name

Zahra Ghasemnejad

Name of organization / entity

Kermanshah University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences, Vice-chancellor for Research and technology

Expected recruitment start date

2013-10-15, 1392/07/23

Expected recruitment end date

2014-03-15, 1392/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative of two surgical methods in the treatment of pediatrics with hydrocele

Public title

Comparative of two surgical methods in the treatment of pediatrics with hydrocele

Purpose

Treatment

Inclusion/Exclusion criteria

The criteria for inclusion of study are: children below 12 years old who are candidates for treatment of hydrocele in Imam Reza hospital of Kermanshah; non-communicating simple hydrocele. The criteria for exclusion of study are: communicating hydrocele and testicular pathology in the same time; opposite testicle cryptorchidism and Inguinal hernia.

Age

To **12 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Kermanshah University of Medical Sciences. Research center

Street address

University Reseach Center, No.2 flat, Shahid Beheshti Blvd, Kermanshah

City

Kermanshah

Postal code

6154896587

Approval date

2012-12-15, 1391/09/25

Ethics committee reference number

42513

Health conditions studied

1

Description of health condition studied

hydrocele

ICD-10 code

N43.3

ICD-10 code description

hydrocele of spermatic cord, testis or tunica vaginalis

Primary outcomes

1

Description

Recurrence

Timepoint

At the first week, third and sixth months

Method of measurement

corresponding to physical examination

Secondary outcomes

1

Description

Hematoma

Timepoint

At the first week, third and sixth months

Method of measurement

corresponding to physical examination

2

Description

Damage to spermatic vessels and cord element

Timepoint

At the first week, third and sixth months

Method of measurement

corresponding to physical examination

3

Description

bleeding

Timepoint

At the first week, third and sixth months

Method of measurement

corresponding to physical examination

4

Description

wound infection

Timepoint

At the first week, third and sixth months

Method of measurement

corresponding to physical examination

Intervention groups

1

Description

hydrocelotomy (The cutting on hydrocele sac that make open and drain the fluid and relieve the hydrocele)

Category

Treatment - Surgery

2

Description

hydrocelectomy (Removal of part or all of a hydrocele sac that causes loss of space of fluid and hydrocele treatment)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza hospital of Kermanshah
Full name of responsible person
Zahra Ghasemnejad
Street address
General surgery ward, Imam Reza hospital, Kermanshah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
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University reseach center, No.2 flat, Shahid Beheshti Blvd, Kermanshah university of medical sciences
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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
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

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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