

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of classic surgery and non-ligation surgery in pediatric herniotomy in children under 12 years old in Imam Reza hospital of kermanshah.

Protocol summary

Summary

The objective of this single blind (patients) clinical trial is to compare recurrence and complication rate between two methods of pediatric hernia repair which are repair without sac ligation (intervention) and repair with sac ligation (control). The main inclusion criterion is the children below 12 years old who are candidates for inguinal hernia surgery in Imam Reza hospital of kermanshah. A total of 200 patients are randomly allocated into two groups of intervention (without sac ligation) or control (with sac ligation). The patients who are more susceptible for recurrence (such as: incarcerated hernia, congested hernia, increased intra-abdominal pressure) are excluded from the study. Both group will be evaluated and compared during six month period of time, for recurrence, hematoma and cord inflammation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109257633N1**

Registration date: **2011-10-27, 1390/08/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-27, 1390/08/05

Registrant information

Name

Vahid Motamedi

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 918 617 8390

Email address

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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

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of classic surgery and non-ligation surgery in pediatric herniotomy in children under 12 years old in Imam Reza hospital of kermanshah.

Public title

A comparative study of classic surgery and non-ligation surgery in pediatric herniotomy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children below age 12 years who are candidates for inguinal hernia surgery Exclusion criteria: incarcerated hernia, congested hernia, increased intra abdominal pressure, peritoneal dialysis, ascites and connective tissue disorders

Age

To 12 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 200

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 Research Center, No.2 flat, Shahid Beheshti Blvd, Kermanshah

City

Kermanshah

Postal code

00988318384185

Approval date

2011-05-09, 1390/02/19

Ethics committee reference number

7/420/6351/پ

Health conditions studied

1

Description of health condition studied

Inguinal hernia

ICD-10 code

K40.9

ICD-10 code description

unilateral or unspecified inguinal hernia,without obstruction or gangrene

Primary outcomes

1

Description

Recurrence

Timepoint

At the first week, first, third and sixth months

Method of measurement

corresponding to physical examination

Secondary outcomes

1

Description

Hematoma

Timepoint

At the first week, and the first, third and sixth months

Method of measurement

corresponding to physical examination

2

Description

Cord inflammation

Timepoint

A the first week, and the first, third and sixth months

Method of measurement

corresponding to physical examination

Intervention groups

1

Description

Control group: classic surgery (hernial sac ligation)

Category

Treatment - Surgery

2

Description

Intervention group: hernial repair without sac ligation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital of Kermanshah

Full name of responsible person

Vahid moetamedi

Street address

General surgery ward, Imam Reza hospital, Kermanshah

City

kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Farid najafi

Street address

University reseach center, No.2 flat, Shahid Beheshti Blvd, 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

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

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Vahid Moetamedi

Position

Resident of general surgery

Other areas of specialty/work

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Full name of responsible person

Omid Amanollahi

Position

Pediatric surgeon

Other areas of specialty/work

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Web page address

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