

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of not opening the external oblique fascia on surgical complications in comparison with surgical method with opening the external oblique fascia in pediatric inguinal hernia surgery

Protocol summary

Summary

The purpose of this study was the investigation into the effect of not opening the external oblique fascia on surgical complications in comparison with surgical method with opening the external oblique fascia in pediatric inguinal hernia surgery. A group of 50 children with inguinal hernia will be considered and randomly divided in two groups each with 25 people and one of the groups will undergo surgery with opening external oblique fascia and other group without opening the external oblique fascia. All the patients will have a short follow-up during surgery and after surgery and the first day after surgery and the first week after surgery for early complication and also a long-term follow-up during the first and six months after surgery for long-term complications. The results will be analyzed by statistical methods. The inclusion criteria: age under 4 years, presence at specified times to be followed-up, and no hernia complication before surgery. Exclusion criteria: age over 4 years, hernia complication before surgery, absence at specified times to be followed-up. The main outcome variable is fewer complications after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012016279N1**
Registration date: **2015-05-02, 1394/02/12**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-02, 1394/02/12

Registrant information

Name

Hormoz Mahmoudvand

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 1322 3004

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Lorestan University of Medical Sciences, Khorramabad

Expected recruitment start date

2014-01-30, 1392/11/10

Expected recruitment end date

2014-07-01, 1393/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of not opening the external oblique fascia on surgical complications in comparison with surgical method with opening the external oblique fascia in pediatric inguinal hernia surgery

Public title

The effect of surgical methods on pediatric groin hernia surgery complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age under 4 years, be present at specified times to track, not complicated before hernia surgery
Exclusion criteria: age over 4 years, before surgery the hernia were complicated, were not present at specified times to track

Age

To 4 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In this study persons were divided in two groups via simple random sampling with using a random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Lorestan University of Medical Sciences

Street address

Research and Technology University

City

khorrabad

Postal code

Approval date

2012-12-22, 1391/10/02

Ethics committee reference number

200/79123

Health conditions studied

1

Description of health condition studied

inguinal hernia in infant

ICD-10 code

K40,K40.0,

ICD-10 code description

Inguinal hernia, Bilateral inguinal hernia, with obstruction, without gangrene, Bilateral inguinal hernia, with gangrene, Bilateral inguinal hernia, without obstruction or gangrene, Unilateral or unspecified inguinal hernia, with obstruction, without gang

Primary outcomes

1

Description

Complications of surgery

Timepoint

During the surgery, immediately after surgery, one day after the surgery, a week after surgery, one month after surgery, six months after surgery

Method of measurement

Physical examination and observation by physician

Secondary outcomes

1

Description

Surgical incision size

Timepoint

During surgery

Method of measurement

Ruler

2

Description

Surgical duration

Timepoint

From the beginning to the end of the surgery

Method of measurement

Stopwatch

3

Description

Relapse after surgery

Timepoint

A week after surgery, one month after surgery, six months after surgery

Method of measurement

Physical examination and observation by physician

Intervention groups

1

Description

Intervention1 (intervention group) : surgery without opening the external oblique fascia, in this surgical procedure the tissues are damaged less since the external oblique fascia is not be entered

Category

Treatment - Surgery

2

Description

Intervention2 (control group) : Surgery with opening the external oblique fascia

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Ashayer Hospital

Full name of responsible person

Hormoz Mahmoudvand

Street address

Department of Surgery, Revolution Street, Shohada Ashayer Hospital, Khorramabad

City

Khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology,
Lorestan University of Medical Sciences

Full name of responsible person

Mohammad Hasan Kaedi

Street address

Vice Chancellor for Research and Technology,
Lorestan University of Medical Sciences,
Khorramabad

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Khorramabad

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 and Technology, Lorestan 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

Lorestan University of Medical Sciences

Full name of responsible person

Hormoz Mahmoudvand

Position

Surgeon

Other areas of specialty/work

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Person responsible for updating data

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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