

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Compared result of two different surgical pediatric herniotomy techniques with and without external fascia opening in children with inguinal hernia

Protocol summary

Summary

This study is a prospective and randomized double-blind clinical trial. The aim of this study is compared result of two different surgical pediatric herniotomy technique with and without external fascia opening in children with inguinal hernia. Total of sample size is 400 children under 12 years old. Inclusion criteria are children undergoing inguinal hernia. The Children with Incarcerated hernia, hydrocele, sliding hernia will be excluded. The patients are randomly divided into two groups by blocked randomization. Patient and assessor of study do not know about grouping patients. This study is 2 trial phase. First group, herniotomy surgery is the Surface into Outer ring and without opening the fascia of external oblique muscle. Second group, herniotomy surgery is opening external oblique fascia and opening channel and closing the bag on the surface of the inner ring. Patient's health status In terms of damage to the nerves and blood vessels and hematoma and seroma and hydrocele and testicular edema, ischemic orchitis and testicular atrophy and climbing testicular will be recorded one week, one month, six months and one year after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041727446N1**
Registration date: **2016-04-29, 1395/02/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-04-29, 1395/02/10

Registrant information

Name

Shaghayegh Sherafatmand

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor For Research Of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-05-04, 1395/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compared result of two different surgical pediatric herniotomy techniques with and without external fascia opening in children with inguinal hernia

Public title

Comparison the results of two surgical methods for the treatment of hernias in children with inguinal hernia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: children with inguinal hernia; children under 12 years old. Exclusion Criteria: incarcerated hernia; hydrocele; sliding hernia; undescended testis; the underlying disease.

Age

To 12 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 400

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Postal code

Approval date

2015-12-05, 1394/09/14

Ethics committee reference number

IR.AJUMS.REC.1394.478

Health conditions studied

1

Description of health condition studied

Inguinal Hernia

ICD-10 code

K40

ICD-10 code description

Inguinal Hernia

Primary outcomes

1

Description

Disease recurrence

Timepoint

one week, one month, six months and one year after surgery

Method of measurement

Visiting patients and physical examination

2

Description

Satisfaction with the operation

Timepoint

one week, one month, six months and one year after surgery

Method of measurement

Visiting patients and physical examination

Secondary outcomes

1

Description

Testicular edema, testicular atrophy, climbing testicular

Timepoint

one week, one month, six months and one year after surgery

Method of measurement

Visiting patients and physical examination

2

Description

Damage to the nerves and blood vessels and hematoma

Timepoint

one week, one month, six months and one year after surgery

Method of measurement

Visiting patients and physical examination

Intervention groups

1

Description

Intervention group: herniotomy surgery is the Surface into Outer ring and without opening the fascia of external oblique muscle.

Category

Treatment - Surgery

2

Description

Control group: herniotomy surgery is opening external oblique fascia and opening channel and closing the bag on the surface of the inner ring.

Category

Recruitment centers**1****Recruitment center****Name of recruitment center**

Khomeini Hospital

Full name of responsible person

Mehran Peyvaste

Street address

Khomeini Hospital, Shahid Ahvazian St., Ahvaz

City

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2**Recruitment center****Name of recruitment center**

Aboozar Hospital

Full name of responsible person

Saeid Hesam

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Aboozar Hospital, Tohid Blv, Zeytun Karmandi, Ahvaz.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice chancellor For Research Of Ahvaz Jundishapur
University of Medical Sciences**Full name of responsible person**

Nader Saki

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University of Medical Sciences, Ground Floor, Central
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Sciences, GolestanBLvd., Ahvaz**City**

Ahvaz

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding sourceVice chancellor For Research Of Ahvaz Jundishapur
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**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Position

Resident of General Surgery

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Pediatric Surgery Subspecialties

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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