Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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
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Ahvaz Jundishapur University of Medical Sciences
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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

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Khomeini Hospital

Full name of responsible person
Mehran Peyvasteh

Street address
Khomeini Hospital, Shahid Ahvazian St., Ahvaz

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Ahvaz

2

Recruitment center

Name of recruitment center
Aboozar Hospital

Full name of responsible person
Saeid Hesam

Street address
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

Street address
Vice chancellor For Research Of Ahvaz Jondishapour University of Medical Sciences, Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

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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
Vice 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
Shaghayegh Sherafatmand

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Resident of General Surgery

Other areas of specialty/work

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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