

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 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

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 2922

Email address

sharafatmand.sh@ajums.ac.ir

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

City

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.

City

Ahvaz

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

City

Ahvaz

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

Position

Resident of General Surgery

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

Postal code

-

Phone

+98 61 3222 2922

Fax

-

Email

shershsh@gmail.com

Web page address

-

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Shahnam Askarpour

Position

Pediatric Surgery Subspecialties

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences, GolestanBLvd., Ahvaz

City

Ahvaz

Postal code

Phone

+61 32222922

Fax

Email

Shahnam-Askarpour@yahoo.com

Web page address

-

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Sanaz Nazari

Position

Nurse Anesthesia

Other areas of specialty/work

Street address

Ahvaz Jundishapur University of Medical Sciences,
GolestanBLvd., Ahvaz

City

Ahvaz

Postal code

Phone

00

Fax

Email

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