

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison between inguinal herniotomies with and without incision of inguinal oblique aponeurosis in male children diagnosed with inguinal hernia

Protocol summary

Study aim

Comparison between two inguinal herniotomies with and without incising external oblique aponeurosis

Design

Clinical trial with parallel groups, single-blind study, randomized by heads or tails using healthy coins on at least 80 boy children

Settings and conduct

Male children with inguinal hernia who refer to the pediatric surgery clinic of Imam Ali Alborz Hospital, will be studied. Before the surgery, the surgeon will provide the parents with a complete explanation and after receiving the written consent form from the patient's guardian, the study process will begin. The choice of surgical procedure for each patient will be based on the heads or tails of healthy coin method, which is a random procedure with equal probability of occurrence. After the surgery, the information will be collected using a researcher-made questionnaire that consists of two parts. single-blind study (heads or tails of coin method)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male children with diagnosed inguinal hernia exclusion criteria: dissatisfaction to participate in the study

Intervention groups

Both inguinal herniotomy surgeries are currently used by pediatric surgeons. Due to the insufficiency of the studies performed in the field of comparing the two methods in terms of complications and surgery time and the preference of one method over the another method, and considering that in the pediatric surgery references, no report has been presented on the priority of the surgical method. On the other hand, the need to choose a surgical method with fewer complications and a shorter time to benefit the patient, it seems necessary to address this issue.

Main outcome variables

1. Time of surgery 2. Complications: Inguinal nerves damages; Vas deferens damage; Abdominal viscera damage; Surgical hematoma; Wound infection; Scrotal edema; Seroma; Hydrocele

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201123049467N1**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

Registrant information

Name

Seyed Ahmad Elahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3250 9256

Email address

elahi84@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between inguinal herniotomies with and without incision of inguinal oblique aponeurosis in male children diagnosed with inguinal hernia

Public title
Comparison between inguinal herniotomies in male children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
male children diagnosed with inguinal hernia
Exclusion criteria:
dissatisfaction to participate in the study

Age
From **1 month** old to **170 months** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: simple Randomization unit: individual Randomization tool: heads or tails by healthy coin

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients who entered the study with informed consent are randomly assigned to one of the two groups of inguinal hernia surgery with or without opening the external oblique muscle fascia by the method of heads or tails by a healthy coin.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee of Alborz University of Medical Sciences

Street address

Office of the Ethics Committee, floor 2, Deputy of Research and Technology, Saffarian Alley, Golshahr St, Karaj, Iran

City

Karaj

Province

Alborz

Postal code

3198764653

Approval date

2020-10-10, 1399/07/19

Ethics committee reference number

IR.ABZUMS.REC.1399.184

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

Complications during inguinal herniotomy

Timepoint

During surgery

Method of measurement

observation of surgeon

2

Description

The short-term complications after inguinal herniotomy

Timepoint

One week after discharge

Method of measurement

Examination of surgeon

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Male children with inguinal hernia who undergo surgery with incision the external oblique muscle aponeurosis.

Category

Treatment - Surgery

2

Description

Intervention group2: Male children with inguinal hernia who undergo surgery without incision the external oblique muscle aponeurosis.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital, Karaj

Full name of responsible person

Seyed Ahmad Elahi

Street address

Imam Ali Hospital, Vali Asr Ave, Esteghlal Blvd, Karaj, Iran

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emamali@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr. Mohammad Noori Sepehr

Street address

Deputy of Research and Technology, Saffarian Alley, Golshahr St, Karaj, Iran

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dr.noorisepehr@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Seyed Ahmad Elahi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Medical students and pediatric surgeons if they have a similar study in other medical centers

From where data/document is obtainable

Seyed Ahmad Elahi Imam Ali Alborz Hospital
Elahi84@gmail.com

What processes are involved for a request to access data/document

The applicant must send his/her request to the mentioned e-mail address and the data files will be provided to him/her within up to one month.

Comments