

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two methods of pediatric herniotomy surgery with and without opening external oblique fascia in Children with inguinal hernia

Protocol summary

Study aim

Comparison of two pediatric herniotomy surgeries with and without external oblique fascia in children with inguinal hernia

Design

A simple, randomized, double-blind clinical trial

Settings and conduct

Hernia surgery in Kashani hospital with two methods of opening the fascia and without opening the fascia

Participants/Inclusion and exclusion criteria

Inguinal hernia Age under 12 years The patient's parents are satisfied with participating in the study Children with incarcerated hernia, hydrocele, undescended testicular sliding hernia; Underlying diseases

Intervention groups

The first group of hernia surgery by opening the external oblique muscle fascia The second group of hernia surgery without opening the external oblique muscle fascia

Main outcome variables

Hernia stick Complications of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210501051149N1**

Registration date: **2021-11-22, 1400/09/01**

Registration timing: **retrospective**

Last update: **2021-11-22, 1400/09/01**

Update count: **0**

Registration date

2021-11-22, 1400/09/01

Registrant information

Name

Hossein Tarverdizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3224 5556

Email address

htarverdizadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

2020-04-18, 1399/01/30

Actual recruitment end date

2020-07-10, 1399/04/20

Trial completion date

2021-03-19, 1399/12/29

Scientific title

Comparison of two methods of pediatric herniotomy surgery with and without opening external oblique fascia in Children with inguinal hernia

Public title

Comparison of two methods of pediatric herniotomy surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inguinal hernia age<12

Exclusion criteria:

Incarcerated hernia Parental dissatisfaction

Age

To 12 years old

Gender

Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **74**
Actual sample size reached: **74**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization and color cards Two cards with different colors were placed in front of the patient and the patient chose one. Each color belonged to one of the two groups The patient information form was also kept by the doctor's secretary and the doctor and the researcher did not know about it.

Blinding (investigator's opinion)
Double blinded

Blinding description
2 cards with different colors are placed in front of the patient and the patient chooses one. Each color belongs to one of 2 groups. Also, the patient information form is kept by the doctor's secretary and the doctor and the researcher do not know about it.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences

Street address
Ayatollah Kashani Hospital.Nurse St.,

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815854469

Approval date
2020-02-23, 1398/12/04

Ethics committee reference number
IR.SKUMS.REC.1398.244

Health conditions studied

1

Description of health condition studied
Pediatric inguinal hernia

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Complications of pediatric inguinal hernia surgery

Timepoint
Day 3,7,30 postoperatively

Method of measurement
Physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Pediatric inguinal hernia surgery in two ways by opening the external oblique muscle fascia and without opening the external oblique muscle

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Kashani Hospital in Shahrekord

Full name of responsible person
Hossein Tarverdizadeh

Street address
Nurse St., Ayatollah Kashani Hospital

City
shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815854469

Phone
+98 38 3226 4832

Email
htarverdizadeh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Mehraban Sadeghi

Street address

Nurse St., Ayatollah Kashani Hospital

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

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Email

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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

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Hossein Tarverdizadeh

Position

General Surgery Resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Nurse St., Ayatollah Kashani Hospital

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Person responsible for scientific inquiries

Contact

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Shahre-kord University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Hossein Tarverdizadeh

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Part of the data includes the results of a share-sharing survey

When the data will become available and for how long

Start of access period one year after publication

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Statistical analysis and research results

From where data/document is obtainable

Shahrekord Medical University

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

Sending a request to the Vice Chancellor for Research of Shahrekord University of Medical Sciences

Comments