

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The efficacy of port-less laparoscopic surgery in reducing costs and length of surgical scar in children with Inguinal hernia

Protocol summary

Study aim

Assessment of the feasibility, safety and potential benefits of laparoscopic repair for congenital inguinal hernia (CIH) in our hospital using portless technique.

Design

Clinical trial with control group, parallel, one blinded, randomized

Settings and conduct

Feasibility of portless laparoscopic repair of the inguinal hernia, conversion rate and need for umbilical port were the main measurements. The data collection tool included a questionnaire with two parts and a checklist of items. All patients were examined after one week, then at 3 and 6 months. This study was conducted at Ali Asghar children`s hospital, Tehran, Iran. The study was conducted one-blinded, so patients and surgical nurses were unaware of how the study groups were assigned.

Participants/Inclusion and exclusion criteria

68 patients with congenital inguinal hernia (CIH) presented to the outpatient clinic and were eligible to be enrolled. Boys under 2 months old for fear of damage to cord structures and children who their parents declined to participate in this study were excluded.

Intervention groups

In the control group, after induction of general anesthesia, a 5 mm port is inserted in the umbilicus and the CO2 gas is continuously connected to the port. Camera is then inserted through the port and the surgical procedure is performed in a standard manner. In the non-port (intervention) group, after induction of general anesthesia, the Veress needle is first inserted into the abdominal cavity through a small umbilical skin incision and the CO2 gas is injected with the appropriate volume and pressure, and after reaching the constant pressure, the needle is removed and without the use of port (the main intervention is the removal of the port), the camera enters into the abdomen and the surgery continues according to the routine.

Main outcome variables

Length of surgical scar : Costs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181023041424N1**

Registration date: **2019-04-17, 1398/01/28**

Registration timing: **retrospective**

Last update: **2019-04-17, 1398/01/28**

Update count: **0**

Registration date

2019-04-17, 1398/01/28

Registrant information

Name

Mohammad Karbalaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6253

Email address

karbalaee.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-15, 1397/10/25

Expected recruitment end date

2019-04-14, 1398/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of port-less laparoscopic surgery in reducing costs and length of surgical scar in children with Inguinal hernia

Public title

The benefits assessment of port-less laparoscopy in pediatric inguinal hernia repair

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with congenital inguinal hernia presented to the outpatient clinic

Exclusion criteria:

Children who their parents declined to participate in this study Male infants less than 2 months old

Age

From **1 month** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

We assign the children to portless (group B) and standard (group A). We have six possible combinations of group assignments regarding to size of block 4. All possible combinations were AABB, ABAB, BAAB, BABA, BBAA and ABBA. At the first, we select one of these arrangements at random and the four eligible admitted children were assigned accordingly in each block. We repeated this process many times to include the eligible children

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are categorized consciously in the intervention groups after being informed consent, but they are unaware of the allocation of the study group. The main investigator, who is the same surgeon and author of the article, is not blind and aware of the allocation of the groups, health care personnel (nurses, Etc.) who are responsible for the care of patients, are also unaware of the allocation of study groups, data collection authorities and those who evaluate the outcome, and the safety committee and data monitoring are unaware of the allocation of groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medica

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2019-01-15, 1397/10/25

Ethics committee reference number

IR.IUMS.FMD.REC.1397.227

Health conditions studied

1

Description of health condition studied

Pediatric inguinal hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

Primary outcomes

1

Description

Length of surgical scar

Timepoint

One month after the operation

Method of measurement

Ruler: Hospital Charts

2

Description

Costs

Timepoint

At the time of discharge

Method of measurement

Hospital charts

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" The intervention in the intervention group is to remove the umbilical port. After induction of general anesthesia, the Veress needle is first inserted into the abdominal cavity through the umbilical skin incision and the CO2 gas is injected with the appropriate volume and pressure, and after reaching the constant pressure, the needle is removed and the gas is cut off, then without the use of port the camera enters into the abdomen and the surgery continues.

Category

Treatment - Surgery

2

Description

"Control group:" After induction of general anesthesia, a 5 mm port is inserted in the umbilicus and the CO2 gas is continuously connected to the port and the gas is fed by the device. The appropriate lens is then inserted into the abdomen through the port and the surgical procedure is performed in a routine manner. (The control group received no intervention and was considered as a comparison group)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar children`s hospital

Full name of responsible person

Mohammad Karbalaeei

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No. 193, Dastgerdi Ave., Modares Highway, Tehran, Iran

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1449614535

Phone

+98 21 2304 6253

Email

karbalaeei.m@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

The vice-chancellor of research and technology at Iran University of Medical Sciences

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mohammad Karbalaeei

Position

Fellow

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

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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

The whole potential data is publishable after being unidentifiable

When the data will become available and for how long

The beginning of the access period from the beginning of 1399 to 6 months after the publication of the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

There are no specific requirements for sending requests for access to data or documentation

From where data/document is obtainable

Tel number: 09381666138 Email

Address:MK.surgeon@yahoo.com

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

After receiving the application by email, the documents and data will be provided to the applicant at most within a week.

Comments