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 Karbalaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6253

Email address

karbalaei.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 Karbalaei

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

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1449614535

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karbalaei.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 Karbalaei

Position
Fellow

Latest degree
Specialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

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Position
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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