Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Laparoscopic Extraperitoneal Appendicostomy: A Modified Laparoscopic Appendicostomy Technique for Antegrade Continence Enema in children

Protocol summary

Study aim

In this study, we aimed to introduce a modified extraperitoneal laparoscopic appendicostomy technique for antegrade continence enema (ACE), which might reduce complications like internal herniation that patients face after open or intraperitoneal techniques.

Design

A randomized, single-blinded, case-controlled study with a parallel-group design of 30 patients, enrolled between December 2019 and February 2019, and median follow-up was about six months.

Settings and conduct

This study was conducted in Shiraz Namazee Hospital. After complete clarification of the study for parents and guardians of patients and completion of their informed consent form, patients underwent one of two types of laparoscopic appendicostomy. The supervisors recorded all the necessary variables without knowing the type of operation.

Participants/Inclusion and exclusion criteria

The study population group consisted of 30 children aged 5-15 years who had functional constipation due to Hirschsprung's disease, and stool incontinence caused by anorectal malformations. The participants were prescribed 3 months of bowel management. All patients with a history of a previous laparotomy, cecal and appendix manipulation, short appendix length, and previous appendectomy were excluded.

Intervention groups

The children were randomly assigned into two groups of case and control, in which the first group underwent laparoscopic intra-peritoneal appendicostomy. In contrast, the second group underwent a modified laparoscopic extraperitoneal appendicostomy.

Main outcome variables

These two groups were compared from the aspect of complete constipation remission or incontinence, ease of catheterization, discharge from appendicostomy, and incidence of stenosis of appendicostomy, need for re-operation and inability of catheterization, number of enemas per day, length of hospital stay, and finally their satisfaction with the operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200907048652N1**
Registration date: **2020-10-05, 1399/07/14**
Registration timing: **retrospective**

Last update: **2020-10-05, 1399/07/14**
Update count: **0**

Registration date

2020-10-05, 1399/07/14

Registrant information

Name

Hamidreza Hosseinpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3631 1594

Email address

hp_hamid@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

2019-12-22, 1398/10/01

Actual recruitment end date

2020-03-19, 1398/12/29

Trial completion date

2020-08-21, 1399/05/31

Scientific title

Laparoscopic Extraperitoneal Appendicostomy: A Modified Laparoscopic Appendicostomy Technique for Antegrade Continence Enema in children

Public title

A MODIFIED LAPAROSCOPIC APPENDICOSTOMY TECHNIQUE

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The study population group consisted of 30 children aged 5-15 years who had functional constipation due to Hirschsprung's disease, and stool incontinence caused by anorectal malformations

Exclusion criteria:

All patients with a history of a previous laparotomy, cecal and appendix manipulation, short appendix length, and previous appendectomy were excluded.

Age

To **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be based on permuted block randomization to control the effect of age and sex. Each block will have 6 capacities, ie, we will have 5 blocks of 6. After that, in each block, people randomly enter one of the laparoscopic surgery groups. Randomization within each block will be based on a table of random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blind study, all patients and observers were not aware of the type of procedures, but their parents were totally informed. In fact, Only the surgeon aware of grouping all patients' guardians, and parents knew the exact possible procedures and completed the informed consent. On the other hand, observers measured patients 'satisfaction with the procedure, as well as information such as patients' need for reoperation, number of enema per day, and stoma leakage from the appendix tube, and they recorded all data by questionnaires and detailed daily observations.

Placebo

Not used

Assignment

Parallel

Other design features

The sample size was based on all available patients who fulfilled the inclusion criteria and were willing to participate in our study. The participants were prescribed 3 months of bowel management.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Shiraz University of Medical Sciences

Street address

unit 2-nastaran bldg-8th alley- azim street- west qodusi blvd

City

Shiraz

Province

Fars

Postal code

7186611555

Approval date

2019-12-21, 1398/09/30

Ethics committee reference number

IR.SUMS.MED.REC.1398.528

Health conditions studied

1

Description of health condition studied

functional constipation

ICD-10 code

K59.0

ICD-10 code description

Constipation

2

Description of health condition studied

Hirschsprung's disease

ICD-10 code

Q43.1

ICD-10 code description

Hirschsprung's disease

3

Description of health condition studied

fecal incontinence

ICD-10 code

R15

ICD-10 code description

Fecal incontinence

4

Description of health condition studied
anorectal malformation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
complete remission of constipation
Timepoint
just after the surgery and 1, 2, and 6 months following the procedure.
Method of measurement
questionnaire

2

Description
ease of catheterization
Timepoint
just after the surgery and 1, 2, and 6 months following the procedure.
Method of measurement
questionnaire

3

Description
stomal leakage
Timepoint
just after the surgery and 1, 2, and 6 months following the procedure.
Method of measurement
questionnaire

4

Description
Stomal stenosis
Timepoint
just after the surgery and 1, 2, and 6 months following the procedure.
Method of measurement
observation and tube test

5

Description
Need for re-operation
Timepoint
just after the surgery and 1, 2, and 6 months following the procedure.
Method of measurement
observation

6

Description
The number of enemas per day
Timepoint
just after the surgery and 1, 2, and 6 months following the procedure.
Method of measurement
questionnaire

7

Description
Days of hospital admission
Timepoint
just after the procedure
Method of measurement
observation

8

Description
Satisfaction rate
Timepoint
just after the surgery and 1, 2, and 6 months following the procedure.
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Following anesthesia, a standard transumbilical approach is as follows. At first, a small orifice was created in the deepest portion of the umbilicus (V skin incision). A Veress needle was inserted into the abdomen, and the air entered the peritoneal cavity. After inserting a 5 mm trocar, the laparoscopic camera was inserted in the umbilicus to evaluate the intra-abdominal cavity and appendix. The second incision was made in the lower left quadrant (LLQ) to introduce the next trocar (5mm). After that, we repositioned the camera and entered the abdomen through the LLQ trocar. Occasionally, we required a third 3mm trocar inserted in the lower right quadrant (LRO) to mobilize and locate the appendix intraperitoneally to the umbilicus for fixation to the skin. To create a cavity and better dissection, 5-10 ml 0.9% Natrium chloride was injected subcutaneously between the abdominal wall and peritoneum under direct observation by laparoscopy, and a dissector was introduced into the newly created cavity through a 5 mm umbilical trocar which was displaced minimally into the new cavity between the peritoneum and abdominal wall. The abdominal wall was dissected and detached from peritoneum toward cecum. Finally, the dissector was entered into the abdominal cavity halfway between the umbilicus and cecum. Then a

Grasper was introduced through an umbilical trocar and the tip of the appendix was taken and pulled through the umbilical port side and fixed to the skin. Subsequently, it worked as a one-way valve. Notably, N/S is injected before dissection of the peritoneum and abdominal wall for a better view of the dissector.

Category

Treatment - Surgery

2

Description

Control group: the control group underwent the conventional type of Laparoscopic Continence Enema, which is somehow similar to our technique except that the appendix duct is pulled out from the intraperitoneal cavity without crossing between the peritoneum and fascia.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazee hospital

Full name of responsible person
Hamidreza Hosseinpour

Street address
Department of Surgery- Namazee square, Zand street

City
Shiraz

Province
Fars

Postal code
7186611555

Phone
+98 71 3631 1594

Email
Hp_Hamid@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamidreza Foroutan

Street address
department of surgery- Namazee Hospital- Namazi square

City
Shiraz

Province
Fars

Postal code
7186611555

Phone
+98 71 3631 1594

Email
forotanh@yahoo.com

Grant name
Shiraz University of Medical Sciences

Grant code / Reference number

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

Title of funding source
Shiraz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

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
Shiraz University of Medical Sciences

Full name of responsible person
Hamidreza

Position
professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatric Surgery

Street address
department of pediatric surgery, Namazee hospital, Namazi square

City
Shiraz

Province
Fars

Postal code
7186611555

Phone
+98 71 3631 1594

Email
forotanh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamidreza Foroutan

Position
professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics
Street address
department of pediatric surgery, Namazee hospital, Namazi square
City
Shiraz
Province
Fars
Postal code
7186611555
Phone
+98 71 3631 1594
Email
forotanh@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamidreza Hosseinpour
Position
Researcher
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Shiraz, Iran
City
shiraz
Province
Fars
Postal code
7186611555
Phone
+98 71 3631 1594
Fax
Email
hp_hamid@ymail.com

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
Undecided - It is not yet known if there will be 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
study design and protocol, statistical process, and the procedure method in detail are planned to share. Patients' information was de-identified prior to data analysis and confidentiality of patient information was guaranteed and protected by recording only the necessary information regarding this study.
When the data will become available and for how long
The data will be available since publishing the manuscript which would be probably right after receiving the Clinical trial code (September 2020)
To whom data/document is available
The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.
Under which criteria data/document could be used
Access to the data means analyzing them at the discretion of the applicant and communicating with the responsible author.
From where data/document is obtainable
Data will be shared just by the corresponding author of the manuscript.
What processes are involved for a request to access data/document
Access to the data will only be possible via email to the responsible author and their response
Comments