

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

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Name of organization / entity

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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	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
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	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% Sodium 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

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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**

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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

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