Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of Laparoscopic surgery in the surgical treatment of patients with ileocolic invagination.

Protocol summary

Study aim
Evaluation of the effect of Laparoscopic surgery in the surgical treatment of patients with ileocolic invagination.

Design
The clinical trial with a control group, with parallel groups, with a sample size of 26 persons per group. The assignment of patients to each group will be applied based on randomization block

Settings and conduct
Selected patients for surgery are randomly divided into two groups. In each group, the surgical team performs the planned actions for each group. After surgery, a researcher liaison (surgical ward nurse) in the operating room and surgical ward will complete the designed questionnaire. Then the researcher will analyze the information obtained. patients and researcher are not aware of the type of intervention performed (open or laparoscopic). This survey is performed in operation room of Tabriz Children"s Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Intussusception Age range between 24-6 months, Irreductable by hydrostatic reduction method. Exclusion Criteria: Any other chronic gastrointestinal diseases, Any other chronic diseases such as diabetes, cardiopulmonary insufficiency, Complete gastro-intestinal obstruction symptoms, Symptoms of peritonitis, High grade fever (above 39 ° C), Long lasting symptoms (more than 48 hours)

Intervention groups
Open surgery group and laparoscopic surgery group

Main outcome variables
Length of surgery time, Duration of hospitalization, The amount of pain after surgery, The time required to start feeding patients after surgery, Surgical site infection rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150124020767N1**
Registration date: **2019-10-06, 1398/07/14**
Registration timing: **prospective**

Last update: **2019-10-06, 1398/07/14**
Update count: **0**

Registration date
2019-10-06, 1398/07/14

Registrant information

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Name of organization / entity
tabriz medical sciences university

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
2019-12-01, 1398/09/10

Actual recruitment end date
2020-04-29, 1399/02/10

Trial completion date
2020-09-05, 1399/06/15

Scientific title
Evaluation of the effect of Laparoscopic surgery in the surgical treatment of patients with ileocolic invagination.

Public title
Evaluation of the effect of Laparoscopic surgery in the treatment of patients with ileocolic invagination.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of intussusception. Age range from 6 to 24 months. Ir-reductable by hydrostatic reduction methods.
Exclusion criteria:
Other types of chronic gastrointestinal diseases. There is any chronic diseases such as diabetes, cardiopulmonary insufficiency. Symptoms of complete gastrointestinal obstruction. Suspicion to peritonitis. Symptom existed for more than 48 hours.
Age
From **6 months** old to **24 months** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **52**
Actual sample size reached: **52**
Randomization (investigator's opinion)
Randomized
Randomization description
Blocked Randomization, Individual random unit, Randomization tool under web (www.randomizer.org), Randomization sequence was made under web (www.radomizer.org), Hiding: Sealed envelope
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients cannot choose their surgical procedure for randomization and the researcher is not aware of the type of intervention performed.
Placebo
Not used
Assignment
Parallel
Other design features
No items

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Tabriz University of Medical Sciences
Street address
Faculty of Medicine, Azadi Street, Golgasht Street, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2019-05-20, 1398/02/30
Ethics committee reference number
IR.TBZMED.REC.1398.178

Health conditions studied

1

Description of health condition studied
Intussusception (reduction)
ICD-10 code
K56.1
ICD-10 code description
Intussusception

Primary outcomes

1

Description
Duration of surgery
Timepoint
During intervention
Method of measurement
Timer

Secondary outcomes

1

Description
Duration of hospitalization
Timepoint
During discharge
Method of measurement
Detection of discharge time by patient examination

2

Description
Pain after surgery
Timepoint
After the patient's consciousness
Method of measurement
Children and Infants Postoperative Pain Scale (CHIPPS)

3

Description
The time it takes for oral nutrition to start
Timepoint
At the start of oral nutrition
Method of measurement

Determining time by examining the patient's clinical condition

4

Description
Surgical site infection
Timepoint
7 days and 30 days after surgery
Method of measurement
Centers for Disease Control and Prevention (CDC) criteria for surgical site infection

Intervention groups

1

Description
Intervention group: Laparoscopic surgery is performed to treat ileocolic intussusception based on existing techniques. After the patient is selected and the anesthesia is performed for him/her, two parts of intestines is separated completely by instruments.Intestine is checked for gangrene and any other injury. Then the operation is terminated
Category
Treatment - Surgery

2

Description
Control group: open surgery is performed to treat ileocolic intussusception based on existing techniques. After the patient is selected and the anesthesia is performed for him/her, two parts of intestines are separated completely by surgeon's hands by milking. Intestine is checked for gangrene and any other injury. Then the operation is terminated
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Children Medical Research & Training Hospital
Full name of responsible person
Masoud Jamshidi
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Children's Hospital, Tabriz, Sheshgolan Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Bahman Rahimi
Position
Resident of general surgery
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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available