

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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, Irreducible 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

Name

masoud jamshidi

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-reducible 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.randomizer.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

Street address

Children's Hospital, Tabriz, Sheshgolan Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

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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

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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