Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The comparative study of the outcomes of early and late oral feeding in intestinal anastomosis surgeries in children

Protocol summary

Summary

Objectives: comparing surgical outcomes of early and late oral feeding in children undergoing intestinal anastomosis. Participants and major eligibility criteria: 66 children aged one month to 12 years in the Imam Reza hospital in Kermanshah are undergoing intestinal resection-anastomosis will be studied; Exclusion criteria included underling diseases, septic shock, severe postoperative ileus (abdominal distention with vomiting), a large difference in size between two ends of the bowel during surgery, complicated surgery, anemia and lack of consistency between weight and age. Design and interventions: In this randomized clinical trial, before surgery, patients are randomly assigned to one of the following groups:In the early feeding group, at first day water and serum dextrose and 2 days after surgery, oral intake of milk and other liquids will begin. In late feeding group, at second day total parental nutrition (TPN) will begin and 5 days after surgery, patients will begin a liquid diet. If appropriate tolerated liquid diet, regular diet gradually will begin. Main outcomes: Patients during the hospital stay will be visited every 12 hours. Duration of hospital stay, time to first defecation and complications after surgery (postoperative fever, nausea, vomiting, abdominal jugular, pneumonia, infections and open incision site) and the cost of hospital patients in both groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107066964N1**
Registration date: **2012-02-16, 1390/11/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-02-16, 1390/11/27

Registrant information

Name
Bahram Azizi
Name of organization / entity
Kermanshah university of medical sciences and health services
Country
Iran (Islamic Republic of)
Phone
+98 83 1427 6309
Email address
dr.ba.azizi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2011-11-06, 1390/08/15

Expected recruitment end date

2012-06-04, 1391/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative study of the outcomes of early and late oral feeding in intestinal anastomosis surgeries in children

Public title

The comparative study of the outcomes of early and late oral feeding in intestinal anastomosis surgeries in children

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: children ranging from one month to 12 years in the imam Reza hospital undergoing surgery with intestinal resection and anastomosis will be enrolled; Exclusion criteria included underling diseases; septic shock; severe postoperative ileus (abdominal distention with vomiting); a large difference in size between two ends of the bowel during surgery; complicated surgery; anemia and lack of consistency between weight and age.
Age
To **12 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee Kermanshah University of Medical Sciences
Street address
Build No. 2 of Kermanshah University of Medical Sciences, Shahid Beheshti Blv, Kermanshah
City
Kermanshah
Postal code
Approval date
2011-06-27, 1390/04/06
Ethics committee reference number
7/420/14127/پ

Health conditions studied

1

Description of health condition studied
Intestinal resection and anastomosis
ICD-10 code
K91.9
ICD-10 code description
Postprocedural disorder of digestive system, unspecified

Primary outcomes

1

Description
Onset time of defecation
Timepoint
every 12h in 5 days post-operation
Method of measurement
Every12 h visits

2

Description
nausea and vomiting and post operation complications
Timepoint
every 12h in 5 days post-operation
Method of measurement
every 12 h visits

Secondary outcomes

1

Description
duration of hospitalization
Timepoint
After patients discharge
Method of measurement
Evaluation of patient document

2

Description
costs of hospitalization
Timepoint
After patients discharge
Method of measurement
Evaluation of patient document

Intervention groups

1

Description
In the early feeding group, at first day water and serum dextrose and 2 days after surgery, oral intake of milk and other liquids will begin.
Category
Treatment - Other

2

Description
In late feeding group, at second day total parental nutrition (TPN) will begin and 5 days after surgery,

patients will begin a liquid diet. If appropriate tolerated liquid diet, regular diet gradually will begin.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital of Kermanshah

Full name of responsible person

Bahram Azizi

Street address

Imamreza hospital, Parastar Blv, Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Build No. 2 of Kermanshah University of Medical Sciences, Shahid Beheshti Blv

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Bahram Azizi

Position

Resident of general surgery

Other areas of specialty/work

Street address

No. 16, District 124, Vahdat Blv

City

Kermanshah

Postal code

6714785474

Phone

+98 83 1427 6309

Fax

+98 83 1427 6301

Email

azizi.ba54@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Omid Amanollahi

Position

Pediatric surgeon

Other areas of specialty/work

Street address

No. 44, District 12, Nastaran St, Shahid Jafari Blv

City

Kermanshah

Postal code

Phone

+98 83 1427 6301

Fax

+98 42 76301

Email

Oamanollahi@kums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Bahram Azizi

Position

Resident of general surgery

Other areas of specialty/work

Street address

No. 16, District 124, Vahdat Blv

City

Kermanshah

Postal code

Phone

+98 83 1427 6309

Fax

+98 83 1427 6301

Email

azizi.ba54@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty