Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison the outcomes of early oral feeding with delayed oral feeding in patients undergoing elective GI surgery

Protocol summary

Study aim
Comparison of the Consequences of Early Oral Nutrition by Late Oral Feeding in Patients with Elective Gastrointestinal Surgery

Design
Clinical trial with control group, with parallel group, randomized Sample size 200 people Randomization in sealed envelope

Settings and conduct
In the field of elective gastrointestinal surgery, Qazvin Hospital, Department of Surgery, the patients were randomly divided into two equal groups of recipients of postoperative early nourishment (24 hours) and control group (under late feeding (5 to 7 days after surgery) And examined

Participants/Inclusion and exclusion criteria
patients undergoing elective digestive surgery Exclusion criteria include certain past medical history such as cirrhosis and roheumatologic disease , taking immonosuppressive drug, malnutrition patient

Intervention groups
Patients were randomly divided into two equal groups of recipients of early-onset nutrition after surgery (24 hours) and control group (under late breastfeeding (5 to 7 days after surgery). In the early feeding group, patients 24 hours after surgery will receive oral fluids, and in the delayed feeding group, a fluid regimen will begin for patients from day 5 after surgery.Patients will be visited every 12 hours during hospitalization and will be evaluated for signs and symptoms of intestinal and abdominal distension, as well as the onset of stool and gastrointestinal symptoms such as nausea and vomiting

Main outcome variables
Anastomotic leaks ; duration of admission ; serum intake ; Incidence of acute edema of the lungs ; infection ; nausea and vomiting ; abdominal pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190529043758N1**
Registration date: **2019-07-28, 1398/05/06**
Registration timing: **retrospective**

Last update: **2019-07-28, 1398/05/06**
Update count: **0**

Registration date
2019-07-28, 1398/05/06

Registrant information
Name
Bahram Shaghaghi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 28 3379 0620
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bahram.shaghaghi@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-08-23, 1396/06/01
Expected recruitment end date
2019-03-21, 1398/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison the outcomes of early oral feeding with delayed oral feeding in patients undergoing elective GI surgery

Public title
Comparison early oral feeding with delayed oral feeding in elective GI surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients undergoing elective digestive surgery (including stomach, small intestine, colon).
Exclusion criteria:
certain past medical history such as cirrhosis and rheumatologic disease taking immunosuppressive drugs malnutrition patients
Age
From **20 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization, individual, sealed envelope
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
Ethics Committee of Qazvin University of Medical Sciences
Street address
Qazvin - Shahid Bahonar Blvd. - Qazvin University of Medical Sciences
City
qazvin
Province
Qazvin
Postal code
15315-34199
Approval date
2018-10-17, 1397/07/25
Ethics committee reference number
ir.qums.rec.1397.162

Health conditions studied

1

Description of health condition studied
Jejunojejunostomy
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Loop gastrojejunostomy + Braun jejunojejunostomy
ICD-10 code
ICD-10 code description

3

Description of health condition studied
Ileoileostomy
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Total colectomy
ICD-10 code
ICD-10 code description

5

Description of health condition studied
choldoduodenostomy
ICD-10 code
ICD-10 code description

6

Description of health condition studied
Jejunoileal anastomosis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Incidence of leaked anastomosis
Timepoint
Daily after operation until discharge
Method of measurement
Physical examination

Secondary outcomes

1

Description
Incidence of acute edema of the lungs
Timepoint
24 hours and 5 days after surgery
Method of measurement
Physical examination

2

Description
Incidence of infection
Timepoint
24 hours and 5 days after surgery
Method of measurement
Physical examination

3

Description
Incidence of nausea and vomiting
Timepoint
24 hours and 5 days after surgery
Method of measurement
Physical examination

4

Description
Incidence of abdominal pain
Timepoint
24 hours and 5 days after surgery
Method of measurement
Physical examination

5

Description
The amount of received serum
Timepoint
24 hours and 5 days after surgery
Method of measurement
Liters

6

Description
The number of hospitalization
Timepoint
24 hours and 5 days after surgery
Method of measurement
date

Intervention groups

1

Description
Intervention group: The oral nutrition begins 24 hours after anastomosis and progresses gradually. (first 24 hours)
Category
Treatment - Surgery

2

Description
Control group: The oral nutrition begins 5 days after anastomosis and progresses gradually. (5 days later)
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
velayat hospital
Full name of responsible person
bahram shaghaghi
Street address
Qazvin University of Medical Sciences - Shahid Bahonar Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
amir peymani
Street address
Qazvin University of Medical Sciences,Shahid Bahonar Blvd
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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
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Bahram Shaghaghi
Position
Residency
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Velayate Hospital,Cooperative Square, Blvd. 22 Bahman,Coah-e-Aliah, Minoodar,Qazvin
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
A portion of the data, such as information about the original outcome, can be shared.
When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

This data is available to researchers at university institutes

Under which criteria data/document could be used

Data can be used if any surgery is maintained

From where data/document is obtainable

Getting the data through Dr. Bahram Shaghaghi is possible bahram.shaghaghi@gmail.com

What processes are involved for a request to access data/document

After submitting the request to the researcher, the data file will be available to applicants within 1-2 months.

Comments