

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 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 rheumatologic disease , taking immunosuppressive 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)

Phone

+98 28 3379 0620

Email address

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

2018-10-17, 1397/07/25

Ethics committee reference number
ir.qums.rec.1397.162

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

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

Ileileostomy

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

Jejunioileal 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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15315-34199

Phone

+98 28 3333 6001

Email

info@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

amir peymani

Street address

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Phone

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Email

info@qums.ac.ir

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

City

Qazvin

Province

Qazvin

Postal code

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Phone

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Fax**Email**

bahram.shaghaghi@gmail.com

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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