

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of nutritional guidelines on the gastrointestinal complications control among patients with open heart surgery

Protocol summary

Study aim

Prevention of gastrointestinal complications among patients after open heart surgery using the nutritional guidelines.

Design

A non-randomized clinical trial with control group, without blinding

Settings and conduct

The location of the study is Baqietollah Hospital. Patients are selected by available sampling method. At first, control group samples are examined for postoperative gastrointestinal complications. After completing the control group sampling, in the same way, patients in the intervention group enter the study and receive intervention. Then they are examined for digestive complications.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 30-75 years old, body mass index less than 30, First time open heart surgery. Non-inclusion criteria: Emergency surgery, previous gastrointestinal problems (such as constipation, diarrhea, chronic abdominal distension, peptic ulcer), Restrictive motor problems, Specific food allergies, long-term mechanical ventilation (greater than 24 hours), Hypotension and the need for hemodynamic support, requiring re-operation

Intervention groups

Intervention group: A nutrition protocol that is developed based on the opinion of the heart surgeon, anesthesiologist, nutritionist and traditional medicine is taught to the patient and their families in two sessions of 1.5 hours. The nutrition protocol is used by the patient from the preoperation time until the discharge. Control group: Control group did not receive intervention.

Main outcome variables

Nausea, vomiting, Abdominal flatulence, Constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190422043349N1**

Registration date: **2019-08-05, 1398/05/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-05, 1398/05/14**

Update count: **0**

Registration date

2019-08-05, 1398/05/14

Registrant information

Name

zari gholami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8272 3295

Email address

stu.gholami.zgh@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of nutritional guidelines on the gastrointestinal complications control among patients with open heart surgery

Public title

The role of nutritional protocol on gastrointestinal complications of patients undergoing open heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age: 30-75 years BMI $\leq$ 30 first-time open heart surgery

Exclusion criteria:

Previous GI problems such as constipation, diarrhea, chronic abdominal distension, peptic ulcer. Presence of food allergies Prolonged mechanical ventilation (longer than 24 hours) Restrictive motor problems Hypotension and the need for hemodynamic support Need surgery again

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical Sciences, No. 26, South Sheikh Bahaei St., Mollasadra Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2019-02-12, 1397/11/23

Ethics committee reference number

IR.BMSU.REC.1397.253

Health conditions studied

1

Description of health condition studied

open heart surgery

ICD-10 code

Z95.1

ICD-10 code description

Presence of aortocoronary bypass graft

Primary outcomes

1

Description

Nausea

Timepoint

Immediately after the open heart surgery until the day of discharge

Method of measurement

Gastrointestinal Evaluation Checklist

2

Description

Vomiting

Timepoint

Immediately after the open heart surgery until the day of discharge

Method of measurement

Gastrointestinal Evaluation Checklist

3

Description

Constipation

Timepoint

Immediately after the open heart surgery until the day of discharge

Method of measurement

Gastrointestinal Evaluation Checklist

4

Description

flatulency

Timepoint

Immediately after the open heart surgery until the day of discharge

Method of measurement

Gastrointestinal Evaluation Checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Training of nutrition guideline (approved by ten experts of Baqiyatallah University of Medical Sciences) in two three-hour sessions to the patient, the patient's family and nursing staff. Then performing this guideline by the patient in three steps before surgery, post operative and before discharge.

Category

Treatment - Other

2

Description

Control group: No training was provided

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Zari Gholami

Street address

Baqiyatallah Hospital, Molla sadra Street, Vanak Sq, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Morteza Khaghanizadeh

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Baqiyatallah University of Medical Sciences, No. 26, South Sheikh Bahaei St, Mollasadra Ave, Tehran

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stu.gholami.zgh@bmsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Zari Gholami

Position

Masters student of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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No. 5, Third closed alley, Borajali Alley, Imam Hussein Street, Vardavard

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stu.gholami.zgh@bmsu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Zari Gholami

Position

Student of nursing mastery

Latest degree

Master

Other areas of specialty/work

Nursery

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Zari Gholami

Position

Master of nursing student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address