Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effect of probiotic supplementation on gut microbiome composition and postoperative pain in patients undergoing open heart surgery

Protocol summary

Study aim
The effect of probiotic supplementation on intestinal microbiome composition and postoperative pain in patients undergoing open heart surgery

Design
Clinical trial with control group, double-blind, randomized, on 100 patients

Settings and conduct
In the hospital of Shahid Beheshti University of Medical Sciences. In this study, patients are divided into 2 intervention groups (as probiotic supplement group) and control group (as placebo group) (named groups A and B), to randomly assign patients to two groups of methods. Stratified blocked randomization is used. The division of branches is based on gender, so that patients are first classified into two groups based on gender: male and female (as 2 to Strata). After specifying the quadruple blocks in different arrangements (AABB, ABAB, ABBA, etc.), the lottery method with placement is used to determine the treatment allocation list.

Participants/Inclusion and exclusion criteria
Willingness to participate in the study and completion of informed written consent, People who, at the discretion of a cardiologist, need open heart surgery, Age over 40 years,Lack of gastrointestinal sensitivity to probiotics, Body mass index greater than 18, Do not drink alcohol or use drugs and anti-inflammatory drugs, Do not take multivitamin and mineral supplements, do not take clozapine, theophylline, caffeine, phenacetine and tacrine,Do not take interfering drugs on the surface of the gut microbiome

Intervention groups
Patients are divided into one of two groups receiving probiotic supplement (1 g daily) and the control group (placebo receiving group). This amount of supplement is considered in the form of 2 tablets of 500 mg daily.

Main outcome variables
Pain after open heart surgery,age

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110510006431N4**
Registration date: **2022-02-16, 1400/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-16, 1400/11/27**
Update count: **0**

Registration date
2022-02-16, 1400/11/27

Registrant information
Name
Mahdi Shadnoush
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 2240 1423
Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of probiotic supplementation on gut microbiome composition and postoperative pain in patients undergoing open heart surgery

Public title
Effect of probiotics on gut microbiome and pain
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study and completion of informed written consent People who, at the discretion of a cardiologist, need open heart surgery Age over 40 years Lack of gastrointestinal sensitivity to probiotics Body mass index greater than 18 Do not drink alcohol or use drugs and anti-inflammatory drugs Do not take multivitamin and mineral supplements, do not take clozapine, theophylline, caffeine, phenacetine and tacrine Do not take interfering drugs on the surface of the intestinal microbiome
Exclusion criteria:
Age
From **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, patients are divided into 2 intervention groups (as probiotic supplement group) and control group (as placebo group) (named groups A and B), to randomly assign patients to two groups of methods. Stratified blocked randomization is used. The division of branches is based on gender, so that patients are first classified into two groups based on gender: male and female (as 2 to Strata). After specifying the quadruple blocks in different arrangements (AABB, ABAB, ABBA, etc.), the lottery method with placement is used to determine the treatment allocation list. It is also necessary to explain that in order to observe the concealment in the mentioned plan, the randomization operation is performed by a person other than the main researcher and the codes specified in the packets in the package after randomization are provided to the researchers for random sampling and assignment. Placed in the intervention or control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is double blind. A person other than the researcher who has no information about how to perform and the purpose of the study will use a list of random numbers to encode the probiotic supplement and placebo and will be numbered according to the list so that the researcher does not know The type of supplements should be observed by each group. Participants will also have no information about the contents of the package.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Beheshti University of Medical Sciences
Street address
Velenjak
City
Tehran
Province
Tehran
Postal code
1985738883
Approval date
2021-06-07, 1400/03/17
Ethics committee reference number
IR.SBMU.RETECH.REC.1400.163

Health conditions studied

1

Description of health condition studied
The amount of pain after open heart surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The degree of pain
Timepoint
Immediately after regaining consciousness, 12 hours and 24 hours later regaining consciousness
Method of measurement
Visual Analog Scale

2

Description
Measurement of gut microbiome

Timepoint
Start and end of the study
Method of measurement
gut microbiome genome sequencing technique

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Familact supplement of bio-fermentation company contains probiotic mixture including 7 stable and frozen strains: Lactobacillus acidophilus CFU (109 × 2), Lactobacillus bulgaricus CFU (108 × 2 (, Lactobacillus ramensus CFU) (Cactus 1), Cactus 109) 109 × 7), Streptococcus thermophilus CFU (1010 × 1.5), Bifidobacterium langum CFU (109 × 7), Bifidobacterium bruvii CFU (1010 × 2) and the prebiotic fructose oligosaccharide will be part of its probiotic activity. 1 gram per day for 14 days
Category
Rehabilitation

2

Description
Control group: Capsules containing starch are quite similar to probiotic capsules,1 gram per day for 14 days
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Modarres hospital
Full name of responsible person
Mahdi Shadnoush
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahdi Shadnoush
Position
Associate professor
Latest degree
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Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Access period starts 3 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Obtain permission and retain the original source name
From where data/document is obtainable
shadnoush@sbmu.ac.ir
What processes are involved for a request to access data/document
Email to the corresponding author
Comments