

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 Shadnough

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2240 1423

Email address

shadnough@sbmu.ac.ir

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 ramensens 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 Shadnough

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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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Email

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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 Shadnough

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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