

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of probiotics in postoperative constipation in bariatric surgery patients

Protocol summary

Study aim

Investigating the effect of probiotic consumption on the rate of constipation after bariatric surgery patients compared with placebo

Design

A control group, with parallel groups, double-blind, randomized, on 27 patients. Patients will be randomized in blocks of four individually using randomization.com site using block randomization method. Allocation concealment will be done by using opaque, sealed, and consecutively numbered envelopes.

Settings and conduct

All patients in the surgery department of Imam Reza Hospital in Mashhad have undergone obesity or bariatric surgery and are divided into two control and intervention groups. Therapeutic intervention is administered in the form of Prodigest 500 mg probiotic capsules (containing Lactobacillus and Bifidobacterium probiotics) daily for 2 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with BMI greater than 40 with or without obesity-related comorbidities Patient with BMI 35-40 with medical comorbidity A patient who has failed a weight loss diet under the supervision of a doctor. The patient is psychiatrically stable Confirmation of patients' constipation based on Rome's criteria after one month of surgery Exit criteria: A disease that makes anesthesia or surgery dangerous for the patient The patient is mentally incompetent to understand the operation technique Inability or unwillingness to change lifestyle after surgery Abuse of certain drugs and alcohol or any other addiction Active bulimia nervosa or other eating disorders The patient is psychiatrically unstable Unsupportive family Non-confirmation of patients' constipation based on Rome's criteria after one month of surgery

Intervention groups

Bariatric surgery patients receiving probiotics Bariatric surgery patients receiving placebo

Main outcome variables

Investigation of constipation and defecation within two months after consuming probiotic digest

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190423043356N4**

Registration date: **2023-08-07, 1402/05/16**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-07, 1402/05/16**

Update count: **0**

Registration date

2023-08-07, 1402/05/16

Registrant information

Name

Amin Dalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 2557

Email address

daliliam@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-06, 1402/05/15

Expected recruitment end date

2024-08-05, 1403/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotics in postoperative constipation in bariatric surgery patients

Public title

The effect of probiotics in postoperative constipation in bariatric surgery patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with BMI greater than 40 with or without obesity-related comorbidities Patient with BMI 35-40 with medical comorbidity A patient who has failed a weight loss diet under the supervision of a doctor The patient is psychiatrically stable Confirmation of patients' constipation based on Rome's criteria after one month of surgery

Exclusion criteria:

A disease that makes anesthesia or surgery dangerous for the patient The patient is mentally incompetent to understand the operation technique Inability or unwillingness to change lifestyle after surgery Abuse of drugs and alcohol or any other addiction Active bulimia nervosa or other eating disorders The patient is psychiatrically unstable Unsupportive family Non-confirmation of patients' constipation based on Rome's criteria after one month of surgery

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 27

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be individually randomized using the block randomization method in quadruple blocks by randomization.com website, Allocation concealment will be done using sealed, opaque, and sequentially numbered envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, The nurse who collects the data, Data analyzer

Placebo

Used

Assignment

Parallel

Other design features

It is a diagnostic and therapeutic method

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Imam Reza Hospital, Ibn-e-Sina St

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2023-05-01, 1402/02/11

Ethics committee reference number

IR.MUMS.IRH.REC.1402.035

Health conditions studied**1****Description of health condition studied**

Morbid Obesity

ICD-10 code

E66.01

ICD-10 code description

Morbid (severe) obesity due to excess calories

Primary outcomes**1****Description**

The severity of constipation

Timepoint

Visit at the end of the first, second, fourth, sixth and eighth week

Method of measurement

Physical examination by the surgeon and according to Rome IV Criteria

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Bariatric surgery patients receiving probiotics

Category

Treatment - Drugs

2**Description**

Control group: Bariatric surgery patients receiving placebo

Category

Placebo

Recruitment centers1**Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Amin Dalili

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Ghoreshi Building, Daneshgah St.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mashhad University of Medical Sciences

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Fellowship of minimally invasive and bariatric surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Fellowship of minimally invasive and bariatric surgery

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

Mashhad University of Medical Sciences

Full name of responsible person

Amin Dalili

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Fellowship of minimally invasive and bariatric surgery

Street address

Imam Reza Hospital

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Province

Razavi Khorasan

Postal code

9137913316

Phone**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

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