

# 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 centers**1**Recruitment center****Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Amin Dalili

**Street address**

Imam Reza Hospital, Ibn-e-Sina St

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+98 51 3851 5255

**Email**

daliliam@mumus.ac.ir

**Sponsors / Funding sources**1**Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Ghoreshi Building, Daneshgah St.

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vcresearch@mums.ac.ir

**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

**Street address**

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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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Surgical Oncology Research Center, Imam Reza Hospital, Mashhad University of Medical Sciences

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**Person responsible for updating data****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

**Street address**

Imam Reza Hospital

**City**

Mashhad

**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