Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the Effectiveness of Synbiotic Supplements on Micronutrient Status after Sleeve Gastrectomy Surgery

Protocol summary

Study aim

Investigating the effectiveness of synbiotic supplements on micronutrient status, gastrointestinal function, metabolic markers including lipid and glucose profiles, weight loss indicators, and quality of life in patients who have undergone Sleeve Gastrectomy surgery.

Design

Phase 3 randomized controlled clinical trial with a parallel-group, double-blind design, conducted on 76 patients. The patients are randomly assigned into two groups using block randomization with the help of the RAND function in Excel.

Settings and conduct

The study, conducted at Shariati hospital in Tehran, will evaluate patients before the intervention, 3 months after starting, and 3 months after completion. Group assignments are randomized, and known only to the product distributor.

Participants/Inclusion and exclusion criteria

This study includes adults aged 18-65 with class 3 obesity or class 2 obesity with an obesity-related condition who have undergone Sleeve Gastrectomy within the past month and are willing to participate. Individuals with a history of nutritional deficiencies, irreversible effects from such deficiencies, or factors interfering with study outcomes will be excluded.

Intervention groups

Intervention: BioGen®, containing strains of Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus plantarum, Streptococcus thermophilus, and Bifidobacterium longum (a total of 10^9 CFU/sachet), combined with 4 grams of inulin every 12 hours for 3 months. Control: starch.

Main outcome variables

Micronutrients (including serum 25-hydroxy vitamin D, serum vitamin B12, serum Folate, total serum Calcium, serum Iron, TIBC, and Ferritin); gastrointestinal function (GIQLI questionnaire); lipid profile (total cholesterol, TG, LDL, and HDL); glycemic profile (FBS and HbA1C); weight loss indicators (%EWL and %TWL); and quality of life (SF-36 questionnaire).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241209063999N1**
Registration date: **2025-03-15, 1403/12/25**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-15, 1403/12/25**
Update count: **0**

Registration date

2025-03-15, 1403/12/25

Registrant information

Name

Mohammadmahdi Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8807 6382

Email address

mm-abbasi@student.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the Effectiveness of Synbiotic Supplements on Micronutrient Status after Sleeve Gastrectomy Surgery

Public title
Investigating the Effects of Synbiotic Supplements on Micronutrients after Sleeve Gastrectomy Surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults (18 to 65 years old) who, according to NIH guidelines, have class 3 obesity or class 2 obesity with at least one obesity-related co-morbidity and have undergone SG surgery within the past month Willingness to adhere to supplement intake and follow-up programs

Exclusion criteria:
Pregnant or lactating women Patients consuming other probiotic/prebiotic supplements, taking antibiotics up to 10 days before the start of the intervention, or using medications that affect gut microbiota The presence of severe malabsorption syndromes unrelated to surgery (inflammatory bowel disease, celiac disease, etc.) Presence of previous nutritional deficiencies Presence of any gastrointestinal diseases Presence of surgical complications (such as fistula at the incision site, gastrointestinal bleeding, intestinal obstruction, etc.) Unable to comprehend the purpose of evaluations or the proposed treatment Patients who refuse to participate in the study until its completion

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are placed in blocks of 4 or 6 and assigned to either the intervention or control group using a computer-generated random sequence. The allocation of patients to each block is based on the following criteria: Gender (male/female) Age (under 40 years and over 40 years) Underlying conditions (diabetes)

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants in each block are randomly divided into two groups, and each is assigned a unique code. Only the individual responsible for distributing the drug/placebo has access to the codes identifying patients in the intervention/control groups. The drug and placebo are prepared in identical packages and consumed in the same manner. The clinical team, which has direct contact with the patients and evaluates the study outcomes, will not have access to the group assignment list. Researchers will not have access to the group codes until data collection is complete.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Dr. Shariati Educational, Research, and Treatment Center, North Kargar St., Jalal Al-Ahmad Intersection, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1411713135

Approval date
2025-03-10, 1403/12/20

Ethics committee reference number
IR.TUMS.EMRI.REC.1403.178

Health conditions studied

1

Description of health condition studied
Obesity

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Serum 25-hydroxy vitamin D

Timepoint
Before the start of the intervention, and 3 and 6 months

after the intervention begins.

Method of measurement

immunoassay

2

Description

Serum vitamin B12

Timepoint

Before the start of the intervention, and 3 and 6 months after the intervention begins.

Method of measurement

Electrochemiluminescence

3

Description

Serum Iron

Timepoint

Before the start of the intervention, and 3 and 6 months after the intervention begins.

Method of measurement

spectrophotometry

4

Description

TIBC (Total Iron-Binding Capacity)

Timepoint

Before the start of the intervention, and 3 and 6 months after the intervention begins.

Method of measurement

spectrophotometry

5

Description

serum Ferritin

Timepoint

Before the start of the intervention, and 3 and 6 months after the intervention begins.

Method of measurement

immunoassay

6

Description

serum Folate

Timepoint

Before the start of the intervention, and 3 and 6 months after the intervention begins.

Method of measurement

Radioimmunoassay

7

Description

Serum total Calcium

Timepoint

Before the start of the intervention, and 3 and 6 months after the intervention begins.

Method of measurement

colorimetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The synbiotic supplement BioGen®, manufactured by Tak Gene Zist, contains strains of Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus plantarum, Streptococcus thermophilus, and Bifidobacterium longum (total 10^9 CFU per sachet) along with 4 grams of inulin (IRC code 2922037751120054). It is administered every 12 hours for a duration of 3 months.

Category

Treatment - Drugs

2

Description

Control group: The placebo, identical in appearance and taste to the synbiotic supplement (contains starch in the same volume as the supplement).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shriati Hospital

Full name of responsible person

Mohammadmahdi Abbasi

Street address

Dr. Shariati Educational, Research, and Treatment Center, North Kargar St., Jalal Al-Ahmad Intersection, Tehran, Iran.

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shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadmahdi Abbasi

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Grant name
Funding for the Obesity and Eating Habits Research Center
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mohammadmahdi Abbasi
Position
Non-faculty Specialist
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Demographic information and study outcomes, including plasma micronutrients and glucose and lipid profiles of the patients, will be published in an anonymized form.

When the data will become available and for how long
6 months after publication of the article.

To whom data/document is available
Anonymized data will be available to researchers for scientific research purposes.

Under which criteria data/document could be used
Anonymized data, with source citation, can be used for future study designs, meta-analysis, and review articles.

From where data/document is obtainable
Applicants can obtain this information by contacting via the following email or fax: Email: mm-abbasi@student.tums.ac.ir Fax: +982188633039 Mohammadmahdi Abbasi - Principal Investigator

What processes are involved for a request to access data/document
After correspondence, the request will be approved by the Research Council of the Obesity and Eating Habits Research Center, and the results will be communicated to the applicant via fax or email within 10-14 days.

Comments