Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of administering probiotic tablets after ROUX-en-Y obesity surgery on gastrointestinal function and metabolic factors and weight changes

Protocol summary

Study aim

Evaluate the effect of administering probiotic tablets for 3 months on gastrointestinal function of patients undergoing ROUX-en-Y surgery during 6 months after surgery.

Design

A double-blinded randomized clinical trial with a parallel group design of 134 patients, enrolled between July 2020 and August 2020, and followed for 6 months.

Settings and conduct

Eligible patients were selected from patients who refer to the clinic of Al-Zahra Hospital. Software:Random Allocation Software 2.0; Numbering sequential from1 to 134 by analyzer. Block randomization consisting 4 patients in each block. Patients categorized to group A,B. Patient get one pocket that been one number and name of group inside.Patients underwent surgical interventions and started receiving medication one week after surgery, with visits at 1wk, 5wk, 9wks and 12wks and 6months after surgery.Biochemical laboratory data such as FBS, HbA1C,TG,mg, Alb,LFT,Vit B12...was measured. Investigation of GI function by Gastrointestinal Quality of Life index questionnaire.

Participants/Inclusion and exclusion criteria

The inclusion criteria were (BMI) ≥ 45 or 35 ≤BMI ≤40 associated with comorbidity. Patients with the following criteria did not enter the study: having evidence of chronic gastrointestinal, hepatic or renal disorders, pregnancy, and breastfeeding. The exclusion criteria were receiving antibiotics, probiotics or probiotic enriched foods, NSAID or insulin within 4 weeks before the study initiation and history of gastrointestinal surgeries.

Intervention groups

Patients receiving medication 1 week after surgery.Patients were given 40 mg pantoprazole mineral supplements according to the protocol of the multivitamin treatment center. After 4 months of surgery, vitamin B12 were prescribed every month. Other necessary supplements were also prescribed.

Main outcome variables

Investigation of GI function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220702055340N1**
Registration date: **2022-11-21, 1401/08/30**
Registration timing: **retrospective**

Last update: **2022-11-21, 1401/08/30**
Update count: **0**

Registration date

2022-11-21, 1401/08/30

Registrant information

Name

Alime Hossein Abdolahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3673 0869

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of administering probiotic tablets after ROUX-en-Y obesity surgery on gastrointestinal function and metabolic factors and weight changes

Public title
Probiotic in ROUX_en_Y obesity surgery on gastrointestinal function and metabolic factors and weight changes
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
BMI ≥ 45 kg/m2 35 ≤BMI ≤40 kg/m2 associated with comorbidity
Exclusion criteria:
having evidence of chronic gastrointestinal, hepatic or renal disorders having evidence of chronic hepatic disorders having evidence of chronic renal disorders Pregnancy Breastfeeding in women Recieving antibiotics, probiotics or probiotic enriched foods, non-steroid anti-inflammatory drugs (NSAID) or insulin within 4 weeks before the study initiation. History of gastrointestinal surgeries
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **134**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients were selected from patients who refer to the clinic of Al-Zahra Hospital. Software:Random Allocation Software 2.0; Numbering sequential from1 to 134 by analyzer. Block randomization consisting 4 patients in each block. Patients categorized to group A,B. Patient get one pocket that been one number and name of group inside. Just pharmacist know about group A and B. pharmacist take them the tablets and then analyzer entered the data
Blinding (investigator's opinion)
Double blinded
Blinding description
The probiotic and placebo were determined by the bio-fermentation pharmaceutical company and the samples in each group were delivered to the researcher after the coding under the names of A and B. the groups were decoded after statistical analysis. In this study, the patients, data collectors and data analysts were unaware of the received interventions.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
No.49, 7th Ave., Sepahan Town.,Hezarjarib Blvd.,Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174614141
Approval date
2020-12-19, 1399/09/29
Ethics committee reference number
IR.MUI.MED.REC.1399.849

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

2

Description of health condition studied
Bariatric surgery
ICD-10 code
Z98.84
ICD-10 code description
Bariatric surgery status

Primary outcomes

1

Description
Gastrointestinal Function

Timepoint
start receiving medication 1 week after surgery and start investigation, 5week after surgery, 9weeks after surgery, 12 week after surgery then 6 month after surgery
Method of measurement
Using of Gastrointestinal Quality of Life index questionnaire.

2

Description
Blood sugar
Timepoint
Before surgery and after surgery for up to 6 months
Method of measurement
Blood test

3

Description
Liver enzyme
Timepoint
Before surgery and after surgery for up to 6 months
Method of measurement
Blood test

4

Description
Triglyceride
Timepoint
Before surgery and after surgery for up to 6 months
Method of measurement
Blood test

5

Description
HbA1C
Timepoint
Before surgery and after surgery for up to 6 months
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group received the probiotic tablets (Familact Co.) daily and started receiving medication one week after surgery until 6 months after surgery.After 4 months of surgery, vitamin B12 were prescribed every month. Other necessary supplements were also prescribed
Category
Treatment - Drugs

2

Description
Control group: Patients underwent bariatric surgery and start receiving placebo one week after surgery and start investigation. Placebo was produced by Zist_Takhmir CO that produce the Femilact. Placebo was produced with the same shape without effective material.After 4 months of surgery, vitamin B12 were prescribed every month. Other necessary supplements were also prescribed.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Hamid melali
Street address
Alzahra hospital, Hezarjarib Blvd
City
Isfahan
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Isfehan
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8174675731
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Hamid Melali
Street address
General Surgery Department,Alzahra hospital, Sofe Blvd.
City
Isfahan
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Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
alzahra@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hamid Melali

Position

Associated professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

General Surgery Department, Alzahra hospital, Sofe Blvd.

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Isfahan

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8174675731

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Email

Hamidmelali@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Alime Hossein Abdolahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

No 49, 7th Ave,. Sepahan Town. Hezarjarib Blvd.

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Email

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Alime Hossein Abdolahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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

Outcome of this study Patients information

When the data will become available and for how long

At the end of the study.

To whom data/document is available

Journals, Medical Schools

Under which criteria data/document could be used

To use for other patients or use for other study

From where data/document is obtainable

Alime Hossein Abdolahi a.abdolahi155@gmail.com
Dr.Hamid melali Hamidmelali@yahoo.com

What processes are involved for a request to access

data/document

They have to explain about their study and how to use our data. They request the formal letter by email, data will send during one week.

Comments