

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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 from 1 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 $35 \leq \text{BMI} \leq 40$ 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)

Phone

+98 31 3673 0869

Email address

a.abdolahi155@gmail.com

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 \geq 45 kg/m² 35 \leq BMI \leq 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 Receiving 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 from 1 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

Isfahan

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 (Famifact 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

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

abdolahi88@hotmail.com

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

Province

Isfahan

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.

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

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.

City

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Postal code

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Phone

+98 31 3673 0869

Email

a.abdolahi155@gmail.com

Person responsible for updating data**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

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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