Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of regular physical activities on the abundance of some selected SCFA-producing bacteria in the intestines of obese people after gastric bariatric surgery

Protocol summary

Study aim

Examining the impact of regular physical activity on the prevalence of specific short-chain fatty acid (SCFA)-producing gut microbes, alongside changes in physiological markers, body composition, and fitness levels in individuals with obesity who have undergone sleeve gastrectomy bariatric surgery.

Design

A clinical trial with an exercise group, non-blinded, randomized, conducted on 45 patients.

Settings and conduct

The study protocol involves the assessment of participants one week before and twelve weeks after surgery. The evaluation includes: Anthropometric, measurements, Quality of life questionnaires, Stool and blood sample collection, Functional tests, Physical activity and diet This study is conducted at Hakim Medical Center

Participants/Inclusion and exclusion criteria

Inclusion criteria Candidates between 20 and 50 years old diagnosed with severe obesity, Scheduled for sleeve gastrectomy procedure, without unmanaged long term health conditions, no previous bariatric surgery exclusion criteria The onset of musculoskeletal issues, debilitating neurological conditions, Implantation of electronic medical devices, Use of medications impacting body weight, Reluctance to cooperate

Intervention groups

Individuals with a body mass index (BMI) exceeding 35, the age of 20 to 50 years old

Main outcome variables

Bariatric surgery significantly alters the gut microbiota composition and metabolic profile in obese individuals, with notable changes in SCFA production. Regular physical activity after surgery can further enhance these beneficial changes, leading to improvements in physiological indicators, physical fitness, and body composition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241103063587N1**
Registration date: **2024-12-05, 1403/09/15**
Registration timing: **prospective**

Last update: **2024-12-05, 1403/09/15**
Update count: **0**

Registration date

2024-12-05, 1403/09/15

Registrant information

Name
Mahdiyeh Zamankhanpour
Name of organization / entity
University of Tehran
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-10, 1403/09/20

Expected recruitment end date

2025-01-19, 1403/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of regular physical activities on the abundance of some selected SCFA-producing bacteria in the intestines of obese people after gastric bariatric surgery

Public title

Investigating the effect of regular physical activities on the bacteria of the intestines of obese people after gastric surgery

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Absence of Unmanaged diabetes, poorly controlled hypertension, Major cardiovascular conditions, advanced pulmonary disease (COPD), Significant physical mobility restrictions, Serious neurological disorders that limit function Avoiding concurrent surgical procedures No previous weight loss surgery

Exclusion criteria:

The progression of musculoskeletal conditions and debilitating neurological disorders that impair an individual's ability to perform functional assessments The start of any medications or supplements that can influence body weight, including Appetite suppressants, Weight-loss supplements (except those specifically prescribed by the post-surgery care team), Cardiovascular medications The presence of cardiac implantable electronic devices (CIEDs), such as pacemakers, implantable cardioverter defibrillators (ICDs), or cardiac resynchronization therapy devices (CRT-Ds), which has been considered a contraindication for bioelectrical impedance analysis (BIA) due to concerns about potential electromagnetic interference A reluctance to maintain collaboration.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

More than 1 sample in each individual

Number of samples in each individual: **2**

Stool samples will be collected from participants at two time points: Pre-operative baseline: Samples obtained before the surgical procedure. Post-operative follow-up: Samples collected three months after the surgery.

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research of the Faculty of Sports Sciences and Health at University of Tehran

Street address

Northern 4th Floor, No 90, Nader Ebrahimi Alley(17) , North Karagar

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Province

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1439834434

Approval date

2024-08-21, 1403/05/31

Ethics committee reference number

ETHIC-202408-1272

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

The impact of bariatric surgery and regular physical activity on the prevalence of Coprococcus bacteria in the gut microbiome of obese patients

Timepoint

Alteration in the prevalence of Coprococcus species within the intestinal microbiome, comparing baseline measurements to those taken three months after intervention.

Method of measurement

Utilizing a specialized kit designed for extracting Deoxyribonucleic acid from fecal samples, followed by analysis using the real-time polymerase chain reaction technique

2

Description
The impact of bariatric surgery and regular physical activity on the prevalence of Roseburia bacteria in the gut microbiome of obese patients

Timepoint
Alteration in the prevalence of Roseburia species within the intestinal microbiome, comparing baseline measurements to those taken three months after intervention.

Method of measurement
Utilizing a specialized kit designed for extracting Deoxyribonucleic acid from fecal samples, followed by analysis using the real-time polymerase chain reaction technique

3

Description
The impact of bariatric surgery and regular physical activity on the prevalence of Ruminococcus bacteria in the gut microbiome of obese patients

Timepoint
Alteration in the prevalence of Ruminococcus species within the intestinal microbiome, comparing baseline measurements to those taken three months after intervention.

Method of measurement
Utilizing a specialized kit designed for extracting Deoxyribonucleic acid from fecal samples, followed by analysis using the real-time polymerase chain reaction technique

4

Description
The change in the abundance of the bacterial genus Alistipes in the gut microbiota of obese individuals after bariatric surgery and after regular physical activity.

Timepoint
Alteration in the prevalence of Alistipes species within the intestinal microbiome, comparing baseline measurements to those taken three months after intervention.

Method of measurement
Utilizing a specialized kit designed for extracting Deoxyribonucleic acid from fecal samples, followed by analysis using the real-time polymerase chain reaction technique

5

Description
The change in the abundance of the bacterial genus Blautia in the gut microbiota of obese individuals after bariatric surgery and after regular physical activity.

Timepoint
Alteration in the prevalence of Blautia species within the intestinal microbiome, comparing baseline measurements to those taken three months after intervention.

Method of measurement
Utilizing a specialized kit designed for extracting Deoxyribonucleic acid from fecal samples, followed by analysis using the real-time polymerase chain reaction technique

Secondary outcomes

1

Description
The Effect of Regular Physical Activity on lipid profile changes in Obese Individuals after Bariatric Surgery

Timepoint
Changes in lipid profile before and 3 months after the intervention

Method of measurement
Utilizing Lipid control kits

2

Description
The Effect of Regular Physical Activity on Glucose Profile Changes in Obese Individuals After Bariatric Surgery

Timepoint
Changes in glucose profile before and 3 months after the intervention

Method of measurement
Utilizing glucose kits

3

Description
Impact of Regular Physical Activity on Fitness Test Outcomes in Post-Bariatric Surgery Patients with Obesity

Timepoint
Changes in physical fitness tests before and 3 months after the intervention

Method of measurement
Functional Capacity Assessment: Method: 12-Minute Walk Test (12MWT), Measurement: Distance covered in 12 minutes. Muscle Strength Evaluation: Method: One-Repetition Maximum (1RM) Tests, Focus: Lower limb muscles. Measurement: Number of repetitions completed. physical Activity Monitoring: Method: Personal Activity Logbook, Measurement: Self-reported activity levels and durations. Balance Assessment: Method: Standardized Balance Tests.

4

Description
The Impact of Regular Physical Activity on Body Composition Changes in Post-Bariatric Surgery Patients with Obesity

Timepoint
Changes in anthropometric factors (weight, body mass index, and body fat percentage) before and 3 months after the intervention

Method of measurement
Utilization of a bioimpedance analysis device, a height measuring device with an accuracy of 1 millimeter, and a scale with an accuracy of 0.01 kilograms

Intervention groups

1

Description

The post-surgical rehabilitation protocol for patients undergoing surgery includes a structured exercise regimen designed to facilitate recovery. Initial Phase (Days 1-4) Walking: Patients start walking based on their tolerance levels. Aerobic Exercise (From Day 5 Onwards) Low to Moderate Intensity: Patients participate in low to moderate-intensity aerobic exercises, primarily walking or using a treadmill. Progression Phase (From Day 15 Onwards) Moderate Intensity Aerobic Exercise: Aerobic activities are intensified to moderate levels, guided by treadmill speed tests and steps per minute, ensuring that heart rates remain within 40% to 60% of the reserved heart rate. Strength Training: Moderate-intensity strength training exercises are introduced, focusing on the upper limbs during the first month. From the second to the third month, training will also include the lower limbs. Strength Training Details, Weights: Initially, light weights (1-2 kg) are used with a high number of repetitions. Every four weeks, weights are increased by 5%, while reducing repetitions. Walking Routine: In the initial four weeks post-surgery, patients gradually increase walking speed and duration, aiming for up to 150 minutes per week while maintaining a Rate of perceived exertion (RPE) between 12 and 14 where higher numbers indicate greater effort. Elastic Band Exercises: Frequency and Duration: Strength training with elastic bands is prescribed for three sessions per week, lasting 20 to 30 minutes each. Targeted Movements: Exercises include shoulder movements such as extension, flexion, abduction, and adduction; and hip movements like abduction, adduction, extension, and flexion. Patients receive an educational booklet that outlines exercise instructions. Progress is assessed through measurements taken one week before surgery and twelve weeks post-surgery.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
مرکز پزشکی حکیم

Full name of responsible person
Alireza Khalaj

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No. 49, Hakim Building, Manzarnajad Street (formerly Niyam), Shariati Street, above Mirdamad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
university of tehran

Full name of responsible person
Alireza Haghighi

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4th northern floor, No 90, Nader Ebrahimi (17) alley, North kargar Street

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mahdiyeh.zmnpur@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
university of tehran

Proportion provided by this source
1

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
University of Tehran

Full name of responsible person
Mahdiyeh Zamankhanpour

Position
Post graduate student

Latest degree
Master

Other areas of specialty/work
Exercise Physiology

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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
Undecided - It is not yet known if there will be a plan to make this available

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