

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation the effect of beta-hydroxy beta-methylbutyrate supplementation on the prevention of postoperative sarcopenia in patients undergoing bariatric surgery: a double-blind clinical trial study

Protocol summary

Study aim

Determining the effect of beta-hydroxy beta-methylbutyrate supplementation on the prevention of postoperative sarcopenia in patients undergoing bariatric surgery.

Design

The clinical trial has a control group, with parallel groups, double-blind, randomized, on 80 patients, with a convenient sampling method, and a table of numbers will be used for randomization.

Settings and conduct

This study will be conducted in patients who are candidates for elective mini-bypass surgery, among patients referred to bariatric surgery clinic in Sina Hospital, Tehran. One of the nurses will be responsible for randomly assigning patients and prescribing supplements for them. In order to carry out this research blindly, the supplements will be completely similar and closed in terms of appearance. Also, HMB supplement and placebo are separated by a specific code from the company, which will be determined after analyzing the results of the code for each group. Researchers and doctors will not know about the studied groups and the type of supplement prescribed.

Participants/Inclusion and exclusion criteria

Entry criteria: 1. Age 18 to 65 years 2. Body mass index 40 to 50 3. Candidate for elective mini-bypass surgery. Exclusion criteria: 1. Severe liver disorder 2. Kidney disorder 3. History of previous bariatric surgery

Intervention groups

People in the intervention group will receive HMB powder in the form of 3 grams per day, and people in the control group will receive a placebo with starch content for 30 days after surgery.

Main outcome variables

The amount of muscle mass, the amount of lean mass

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200301046655N4**

Registration date: **2023-08-28, 1402/06/06**

Registration timing: **prospective**

Last update: **2023-08-28, 1402/06/06**

Update count: **0**

Registration date

2023-08-28, 1402/06/06

Registrant information

Name

Razieh Khalooeifard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5975

Email address

shkhalooei1367@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of beta-hydroxy beta-methylbutyrate supplementation on the prevention of postoperative sarcopenia in patients undergoing bariatric surgery: a double-blind clinical trial study

Public title

Investigating the effect of beta-hydroxy beta-methylbutyrate in bariatric surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for mini bypass surgery Body mass index 40 to 50

Exclusion criteria:

Absence of severe hepatic impairment Absence of renal impairment Previous history of bariatric surgery

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this trial, the balanced random block method will be used, with a block size of 4 (combination of A and B as groups). Using the website Randomization.com, random allocation will be done for 80 people in the form of 20 blocks of 4. Since body mass index is an important variable in the intervention effect. This intervention will be implemented in a classified manner. In order to carry out this experiment correctly, a random allocation list will be produced separately for each of the two classes of body mass index 40 to 45 and 45 to 50.

Blinding (investigator's opinion)

Double blinded

Blinding description

One of the nurses will be responsible for randomly selecting patients and prescribing supplements for them. In order to carry out this research blindly, the supplements will be completely similar and closed in terms of appearance. Also, HMB supplement and placebo are separated by a specific code from the company, which will be determined after analyzing the results of the code for each group. Researchers and doctors will not know about the studied groups and the type of supplement prescribed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics committee of Sina Hospital

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2023-08-20, 1402/05/29

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1402.065

Health conditions studied

1

Description of health condition studied

Mini bypass surgery

ICD-10 code

Bariatric

ICD-10 code description

Z98.84

Primary outcomes

1

Description

muscle mass

Timepoint

Before surgery, 1, 3 and 6 months after surgery

Method of measurement

Bioimpedance analyzer

2

Description

Lean mass

Timepoint

Before surgery, 1, 3 and 6 months after surgery

Method of measurement

Bioimpedance analyzer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will receive beta-hydroxy beta-methylbutyrate (HMB) powder (Karen Company) at the rate of 3 grams per day for 30 days after surgery.

Category

Prevention

2

Description

Control group: They will receive placebo with starch content (Karen company) for 30 days after surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Razieh Khalooeifard

Street address

Imam Khomeini St, Hassan Abad Square

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hosp_sina@sina.tums.ac.ir

Web page address

https://sinahospital.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Keshavarz Blvd., Qods Corner, Tehran University of Medical Sciences Headquarters

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vcr@sina.tums.ac.ir

Web page address

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Grant name

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

Razieh Khalooeifard

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Razieh Khalooeifard

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable