

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of glutamine supplementation on the Rectus Femoris and Vastus Intermedius muscles thickness in patients undergoing laparoscopic sleeve gastrectomy

Protocol summary

Study aim

Investigating the effect of glutamine supplementation on muscle mass changes in Rectus Femoris and Vastus Intermedius muscles in patients undergoing laparoscopic sleeve gastrectomy.

Design

This clinical trial has a control group with parallel groups, double-blind, where patients and researchers will be unaware of the type of intervention, randomized online and through the website www.randomization.com, without phase and on 30 patients under laparoscopic sleeve surgery will be performed.

Settings and conduct

The study will be conducted in the surgical department of Shahid Modares Hospital. Patients referred for laparoscopic sleeve after surgery will receive glutamine supplement or placebo in the same packaging labeled A and B. Labeling will be done by a third person and the researcher and patient will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age 64-20 2. BMI $\geq$ 40 before surgery
exclusion criteria: 1. Existence of conditions that can affect muscle mass, such as myopathy. 2. Existence of simultaneous severe pathology 3. Using drugs that can affect muscle mass, such as corticosteroids 4. Active abuse of drugs or alcohol 5. Lack of consent to participate in the study 6. The patient has already undergone bariatric surgery

Intervention groups

Intervention group: 15 patients who will take glutamine for 8 weeks after surgery. Control group: 15 patients who will receive placebo for 8 weeks after surgery.

Main outcome variables

Decrease in muscle mass of rectus femoris and vastus intermedius muscles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230626058586N6**

Registration date: **2024-10-13, 1403/07/22**

Registration timing: **prospective**

Last update: **2024-10-13, 1403/07/22**

Update count: **0**

Registration date

2024-10-13, 1403/07/22

Registrant information

Name

Nasim Sohrabifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 938 229 6766

Email address

nasimsohrabifar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-20, 1403/11/01

Expected recruitment end date

2025-04-21, 1404/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of glutamine supplementation on the Rectus Femoris and Vastus Intermedius muscles thickness in patients undergoing laparoscopic sleeve gastrectomy

Public title

The effect of glutamine on muscle mass

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients in the age range of 20-64 BMI ≥ 40 before surgery

Exclusion criteria:

The presence of other conditions that can affect muscle mass, such as myopathies Presence of concurrent severe underlying disease Using drugs that can affect muscle mass, such as corticosteroids Active abuse of drugs or alcohol Lack of consent to participate in the study Patients who undergo bariatric surgery for the second time

Age

From **20 years** old to **64 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The website www.Randomization.com will be used for randomization (online randomization). After determining the number of intervention groups, which are two groups, and the required number in each of these groups, the website will provide us with a random table of numbers that will represent the patient's number. Then the random sequence is available to the researcher. The researcher performs the desired intervention based on the order in which the participants entered the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Glutamine supplement and placebo will be labeled by a third person in similar packages with the names A and B and will be provided to the patient by a blinded researcher. The researcher and the patient will be unaware of the content of the supplement.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Ethics Committee of Shahid Beheshti University of Medical Sciences, Shahid Beheshti University of Medical Sciences, Arabi St., Student Blvd., Velenjak st., Tehran.

City

Tehran

Province

Tehran

Postal code

1995825466

Approval date

2024-08-18, 1403/05/28

Ethics committee reference number

IR.SBMU.RETECH.REC.1403.237

Health conditions studied

1

Description of health condition studied

Decreased muscle mass

ICD-10 code

M70

ICD-10 code description

Soft tissue disorders related to use, overuse and pressure

Primary outcomes

1

Description

Reduction of Vastus Intermedius and Rectus Femoris muscle mass, which will be measured by ultrasound

Timepoint

Measurement of Vastus Intermedius and Rectus Femoris muscle mass by ultrasound before gastrotomy surgery and 8 weeks after surgery.

Method of measurement

Muscle mass will be measured by SuperSonic ® MACHTM20 ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients undergoing laparoscopic gastrotomy who consume 30 grams of glutamine powder daily for 8 weeks 10 days after surgery

Category

Prevention

2

Description

Control group: Patients undergoing laparoscopic gastrotomy who take 30 grams of Maltodextrin powder a day for 8 weeks 10 days after surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres hospital

Full name of responsible person

Dr. Naser Malekpour Alamdari

Street address

Shahid Modarres Hospital, Saadat Abad Blvd.

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1998734383

Phone

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Nassermalekpour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Naser Malekpour Alamdari

Street address

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199852468

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Naser Malekpour Alamdari

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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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