

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Selected training and Nano-Curcumin Supplementation on some Blood Factors in Patients after Bariatric Surgery

Protocol summary

Study aim

The Effect of Selected Training and Nano-Curcumin Supplementation on LDL, HDL, Triglycerides, Body Fat Percentage, Ferritin, Albumin, Hemoglobin, ALT, and AST Levels in Post-Bariatric Surgery Patients

Design

Study Design: A phase 2, randomized, parallel-group, single-blind clinical trial conducted on 80 post-bariatric surgery patients aged 30-45 years. Randomization will be performed using the RAND function in Excel software.

Settings and conduct

The research will be conducted at the Tehran Minimally Invasive Surgery Research Center using a semi-experimental pretest-posttest control group design

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Obese men and women (BMI thirty or higher) aged thirty to forty-five years with no unstable hemodynamic conditions or mobility disorders and no underlying medical conditions including advanced pulmonary or kidney diseases liver cirrhosis hepatitis or gastrointestinal disorders such as celiac disease or diverticulosis who do not use medications tobacco or alcohol and have completed the PAR-Q questionnaire
Exclusion Criteria: Allergy to nano-curcumin or related plant species reoperation cases use of alcohol or specified medications including metformin levothyroxine cortisone or topiramate within one month prior to study unwillingness to continue participation missing more than three training sessions or more than two nano-curcumin doses any health risks identified by physician during study protocol

Intervention groups

Training group Nano-curcumin consumption group
Training + Nano-curcumin consumption group Control group

Main outcome variables

The study will measure LDL HDL triglycerides body fat percentage ferritin albumin hemoglobin ALT and AST levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250420065394N1**

Registration date: **2025-04-28, 1404/02/08**

Registration timing: **prospective**

Last update: **2025-04-28, 1404/02/08**

Update count: **0**

Registration date

2025-04-28, 1404/02/08

Registrant information

Name

Mohammadreza Goshtasbi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8809 8815

Email address

goshtasbimohammadreza@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2025-06-22, 1404/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Selected training and Nano-Curcumin Supplementation on some Blood Factors in Patients after Bariatric Surgery	
Public title	The Effect of Selected training and Nano-Curcumin Supplementation on some Blood Factors in Patients after Bariatric Surgery
Purpose	Basic science
Inclusion/Exclusion criteria	
Inclusion criteria:	Obese men and women (BMI ≥ 30) Absence of medically unstable hemodynamic conditions Absence of movement disorders No underlying conditions such as advanced pulmonary/kidney diseases, liver cirrhosis, hepatitis, or gastrointestinal disorders (e.g., celiac disease, diverticulosis) No use of medications, tobacco, alcohol, or supplements Completing the PRQ form for more accurate assessment of physical health in individuals
Exclusion criteria:	Individuals allergic to nano-curcumin or other plants of the Zingiberaceae family Second surgery Use of alcohol and medications (metformin, levothyroxine, cortisone, and topiramate) within 1 month prior to the study Unwillingness to continue participation in the study Absence from more than three research sessions or failure to take nano-curcumin capsules more than twice Occurrence of any health risks or complications for patients during the study protocol implementation, as confirmed by the attending physician Age Range: 30-45 years
Age	From 30 years old to 45 years old
Gender	Both
Phase	3
Groups that have been masked	No information
Sample size	Target sample size: 80
Randomization (investigator's opinion)	Not randomized
Randomization description	
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Factorial
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Research Ethics Committees of Islamic Azad University- East Tehran Branch
Street address	Unit 2, 3rd Floor, Tower No. 11, Sina Complex, Iran Zamin Street, Shahrak-e Gharb, Tehran, Iran
City	Tehran
Province	Tehran
Postal code	1465896460
Approval date	2025-03-10, 1403/12/20
Ethics committee reference number	IR.IAU.ET.REC.1404.003
Health conditions studied	
<u>1</u>	
Description of health condition studied	Patients after Bariatric Surgery
ICD-10 code	E66.8
ICD-10 code description	Other obesity
Primary outcomes	
<u>1</u>	
Description	Low-density lipoprotein
Timepoint	Measurements will be conducted at baseline (pre-intervention) and 60 days after initiating nano-curcumin supplementation and the selected training protocol.
Method of measurement	Measurements will be performed using standard laboratory kits.
<u>2</u>	
Description	high-density lipoprotein
Timepoint	Measurements will be conducted at baseline (pre-intervention) and 60 days after initiating nano-curcumin supplementation and the selected training protocol.
Method of measurement	Measurements will be performed using standard laboratory kits.
<u>3</u>	
Description	Ferritin
Timepoint	Measurements will be conducted at baseline (pre-

intervention) and 60 days after initiating nano-curcumin supplementation and the selected training protocol.

Method of measurement

Measurements will be performed using standard laboratory kits.

4

Description

Albumin

Timepoint

Measurements will be conducted at baseline (pre-intervention) and 60 days after initiating nano-curcumin supplementation and the selected training protocol.

Method of measurement

Measurements will be performed using standard laboratory kits.

5

Description

Hemoglobin

Timepoint

Measurements will be conducted at baseline (pre-intervention) and 60 days after initiating nano-curcumin supplementation and the selected training protocol.

Method of measurement

Measurements will be performed using standard laboratory kits.

6

Description

Alanine Aminotransferase

Timepoint

Measurements will be conducted at baseline (pre-intervention) and 60 days after initiating nano-curcumin supplementation and the selected training protocol.

Method of measurement

Measurements will be performed using standard laboratory kits.

7

Description

Aspartate Aminotransferase

Timepoint

Measurements will be conducted at baseline (pre-intervention) and 60 days after initiating nano-curcumin supplementation and the selected training protocol.

Method of measurement

Measurements will be performed using standard laboratory kits.

8

Description

Triglyceride

Timepoint

Measurements will be conducted at baseline (pre-intervention) and 60 days after initiating nano-curcumin supplementation and the selected training protocol.

Method of measurement

Measurements will be performed using standard laboratory kits.

9

Description

body fat percentage

Timepoint

Measurements will be conducted at baseline (pre-intervention) and 60 days after initiating nano-curcumin supplementation and the selected training protocol.

Method of measurement

Body fat percentage will be measured using the InBody 570 device.

Secondary outcomes

1

Description

Palatable Food Craving Questionnaire - Trait (PFQ-T)

Timepoint

The questionnaire will be administered at baseline (pre-intervention) and 60 days after initiating nano-curcumin supplementation and the selected training protocol.

Method of measurement

The PFQ-T questionnaire will be completed by patients before and after the research protocol, with all resulting data collected.

Intervention groups

1

Description

Intervention Group Protocol:1. Nano-curcumin Supplementation: - Initiation: 1 month post-bariatric surgery - Product: Sina Curcumin brand - Dosage: 40 mg twice daily (with meals) - Tablet specification: Each tablet contains 40 mg nano-curcumin - Duration: 60 days2. Exercise Training: - Frequency: 3 sessions/week - Program duration: 60 days - Session components: - Warm-up - Cool-down - Resistance training - Aerobic exercise - Progressive overload: - Week 1 intensity: 50-60% of maximum heart rate (HRmax) - Final week intensity: 65-70% of HRmax - Weekly increases in both duration and intensity

Category

N/A

2

Description

Intervention Group Protocol:Post-bariatric surgery patients will begin nano-curcumin supplementation (Sina Curcumin brand) at 1-month postoperative, administered as: Dosage: 40 mg twice daily (total 80 mg/day) Formulation: 40 mg tablets (one tablet per dose) Administration: With meals Duration: 60 consecutive days

Category

N/A

3

Description

Exercise Protocol: The selected training program will be performed three times per week for 60 days. Each session will include warm-up, cool-down, resistance training, and aerobic exercises. Training duration and intensity will progressively increase weekly, with intensity rising from 50-60% of maximum heart rate in week 1 to 65-70% of maximum heart rate in the final week.

Category

Rehabilitation

4

Description

Control group: No intervention takes place.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Minimally Invasive Surgery Research Center

Full name of responsible person

Mohammad Reza Goshtasbi

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Unit 2, 3rd Floor, Tower No. 11, Sina Complex, Iran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Shokoh Rashvand Samyari

Street address

Unit 2, 3rd Floor, Tower No. 11, Sina Complex, Iran
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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

Islamic Azad University

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohammad Reza Goshtasbi

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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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