Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Selected training and Nano-Curcumin Supplementation on some Blood Factorsin 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 Nanocurcumin consumption group Training + Nanocurcumin 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 Factorsin Patients after Bariatric Surgery

Public title

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

Purpose

Basic scienece

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

1

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

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1465896460

Approval date

2025-03-10, 1403/12/20

Ethics committee reference number

IR.IAU.ET.REC.1404.003

Health conditions studied

1

Description of health condition studied

Patients after Bariatric Surgery

ICD-10 code

E66.8

ICD-10 code description

Other obesity

Primary outcomes

1

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.

2

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.

3

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 Zamin Street, Shahrak-e Gharb, Tehran, 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 Zamin Street, Shahrak-e Gharb, Tehran, 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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Position
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Latest degree
Master

Other areas of specialty/work
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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