

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of High protein-High Fat and High protein-High Carbohydrate meals on the Resting metabolic rate and Metabolic factors in over weight and obese adults

Protocol summary

Study aim

evaluations and comparing the acute effect of two low-calorie high-protein meals with different fat and carbohydrate content on resting metabolic rate and metabolic and blood factors in overweight and obese objects

Design

The clinical trial study is carried out in a cross-over manner and without blinding, and 30 men and women aged 18-65 years received intervention 1 in the first stage, and a week later the same people came again to receive the second intervention. To apply randomization from The method of random blocks will be used with the help of www.randomizer.org

Settings and conduct

The study is soon to be conducted at the Health Monitoring Center of Imam Reza Hospital in Mashhad. Participants, 10 hours fasting, will undergo anthropometric evaluation and indirect calorimetry on the day of their visit. Basic blood tests will also be conducted. After the initial evaluation, participants are to consume the first meal within 15 minutes. Subsequently, 15 minutes later, indirect calorimetry and blood sample tests will be performed. Calorimetry and tests are then to be conducted at 1, 2, 3, and 4 hours post-meal as described. One week after the first intervention, the same participants are scheduled to return to receive the second meal, and evaluations will be conducted in the same manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All adults with overweight and obesity who do not have any underlying conditions
Exclusion criteria: obese and overweight people who have an underlying disease

Intervention groups

Eligible cases are selected and given a high-protein, high-fat, low-carbohydrate meal according to the

protocol, and acute phase evaluations (post prandial) are performed. After one week of the first phase intervention, the same objects receive a high-protein, low-fat, high-carbohydrate meal, and evaluations are performed similarly to the first phase

Main outcome variables

Resting Metabolic rate; Respiratory Quotient; Blood Glucose; Thyroid Hormones; Serum Insulin; Lipid profile; Adrenal hormones - Measurement and comparison of appetite within and between groups

General information

Reason for update

One of the devices utilized in this project for assessing resting metabolic rate is the indirect calorimetry device. Considering that access to this device for students of Mashhad University of Medical Sciences is only available at the university's Employee Health Monitoring Center, and given that the device has been undergoing repairs and was non-operational for some time, as well as the high demand for its use, permission for utilizing the device for this study has only recently been obtained. Therefore, if possible, the patient recruitment phase will be adjusted according to the latest updates.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240106060633N1**
Registration date: **2024-01-20, 1402/10/30**
Registration timing: **prospective**

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

Update count: **1**

Registration date

2024-01-20, 1402/10/30

Registrant information

Name

Saber Sahebi

Name of organization / entity		Age	
Country	Iran (Islamic Republic of)		From 18 years old to 65 years old
Phone	+98 51 3882 7034	Gender	Both
Email address	sahebis921@mums.ac.ir	Phase	N/A
Recruitment status		Groups that have been masked	No information
Recruitment complete		Sample size	Target sample size: 30
Funding source		Randomization (investigator's opinion)	N/A
Expected recruitment start date	2024-10-22, 1403/08/01	Randomization description	
Expected recruitment end date	2025-01-20, 1403/11/01	Blinding (investigator's opinion)	Not blinded
Actual recruitment start date	empty	Blinding description	
Actual recruitment end date	empty	Placebo	Not used
Trial completion date	empty	Assignment	Crossover
Scientific title	The effect of High protein-High Fat and High protein-High Carbohydrate meals on the Resting metabolic rate and Metabolic factors in over weight and obese adults	Other design features	
Public title	The effect of high protein meal on metabolism	Secondary Ids	empty
Purpose	Treatment	Ethics committees	
Inclusion/Exclusion criteria		<u>1</u>	
Inclusion criteria:	18 ≤ age <65 25 ≤ BMI <40 Weight stability for 3 months before starting the study (no more than 5% weight loss or weight gain) Without history of bariatric surgery No use of weight loss medicine in the last 6 months Not using a weight loss diet in the last 3 months The participant should be in complete health, as stated by the individual. They should not have known gastrointestinal diseases and reflux, diabetes, hypertension, cardiovascular diseases, Liver and Kidney disorders, or lipid disorders, nor should they be taking medications related to these conditions. Additionally, they should not be using thyroid medications or other drugs that affect metabolism. Should not engage in intense physical activity and should not be professional athletes (MET-min/week > 600) Should not have addiction to drugs or alcohol Should not have mental health disorders such as depression and eating disorders Should not be pregnant or breastfeeding Willingness to Lose Weight and Consent to Participate in the Program	Ethics committee	
Exclusion criteria:	Intense physical activity before the study Not fasting before intervention Unbalanced diet in terms of composition of macronutrients in the last 24 hours Continuous use of any drug (especially drugs that affect metabolism such as thyroid drugs, drugs that affect Adrenals such as corticosteroids or drugs and alcohol on a continuous basis) Reluctance to cooperate Kidney disorders, Liver failure, lipid profile disorders, lack of micronutrients	Name of ethics committee	Ethics committee of Mashhad University of Medical Sciences
		Street address	Mashhad University of Medical Sciences, school of medicine, Azadi square
		City	Mashhad
		Province	Razavi Khorasan
		Postal code	9177948564
		Approval date	2023-11-07, 1402/08/16
		Ethics committee reference number	IR.MUMS.MEDICAL.REC.1402.411
		Health conditions studied	
		<u>1</u>	
		Description of health condition studied	Overweight and Obesity
		ICD-10 code	E66
		ICD-10 code description	Overweight and obesity

Primary outcomes

1

Description

Resting Metabolic Rate

Timepoint

Resting Metabolic Rate is measured at the beginning of the study, 1, 2, 3 and 4 hours after the intervention.

Method of measurement

The measurement of resting metabolic rate is done by an indirect calorimetry device

Secondary outcomes

1

Description

Respiratory quotient

Timepoint

Similar to measuring Resting Metabolic Energy

Method of measurement

Similar to measuring Resting Metabolic Energy

2

Description

Blood sample variables

Timepoint

Similar to measuring Resting Metabolic Energy

Method of measurement

Similar to measuring Resting Metabolic Energy

Intervention groups

1

Description

Intervention group: In the first phase, objects are given a high-protein (25%) high-fat (45%) low-carbohydrate (30%) meal. The calories of this meal are calculated based on 25% of a person's daily energy requirement.

Category

Treatment - Other

2

Description

Control group: In the second phase, the same objects participating in the first stage as the control group are given a high protein (25%) low fat (15%) high carbohydrate (60%) meal. The calories of this meal are also calculated based on 25% of a person's daily energy requirement.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

MUMS Persian Cohort Study

Full name of responsible person

Mohsen Nemati

Street address

Mashhad University of Medical Sciences, school of medicine, Azadi square

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sahebis921@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

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tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Saber Sahebi

Position

MD-PhD student

Latest degree

Medical doctor

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Person responsible for scientific inquiries

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Full name of responsible person

Saber Sahebi

Position

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Latest degree

Medical doctor

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