

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Examination of influence of macronutrients composition on metabolic responses and arterial stiffness indexes during postprandial phase in lean and obese adults

Protocol summary

Study aim

Examination of influence of macronutrients composition on metabolic responses and arterial stiffness indexes during postprandial phase in lean and obese adults

Design

crossover clinical trial

Settings and conduct

mam reza hospital, mashhad, iran

Participants/Inclusion and exclusion criteria

The inclusion criteria will be: 1. Aged 18-35 years 2. Lean adult include: with a BMI of 18.5-23.5 kg/m², body fat percent between 12-22%, waist circumference <90cm; obese adult include: with a BMI>27.5 kg/m², body fat percent > 27%, waist circumference >90cm. 3. Men 4. Signing the Written informed consent 5. willing to undertake required fasting durations Exclusion criteria will be: 1. Professional athlete 2. change in body weight greater than 10% in 6 months past 3. Current smoking 4. use of medications that might affect study outcomes such as hypo and hyper thyroid and caffeine. 5. history of cardiovascular events (acute myocardial infarction, stroke, etc.), hypertension, diabetes mellitus, dyslipidaemia, pharmacological treatment for any of these conditions, neurological and/or neuropsychological disease or the consumption of toxic substances 6. Use of supplement for weight loss and weight gain 7. who cannot consume test meals due to intolerances/dietary preferences (i.e. vegan, gluten, milk proteins).

Intervention groups

3 test meals include: protein rich, carbohydrate rich and fat rich We will design a crossover clinical trial where each subject (lean and obese men) will complete three interventions (high carbohydrate, high fat meal and high protein meal) with a washout period of one week between each trial.

Main outcome variables

thermic effect of the test meals, Resting measurements

of energy expenditure and substrate, lipide profile, insulin, blood sugar, arterial stiffness index including: pulse wave velocity, augmentation index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190818044552N1**

Registration date: **2019-08-29, 1398/06/07**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-29, 1398/06/07**

Update count: **0**

Registration date

2019-08-29, 1398/06/07

Registrant information

Name

safieh firouzi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3332 3364

Email address

firouzis951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examination of influence of macronutrients composition on metabolic responses and arterial stiffness indexes during postprandial phase in lean and obese adults

Public title

Examination of influence of macronutrients composition on metabolic responses and arterial stiffness indexes during postprandial phase in lean and obese adults

Purpose

Other

Inclusion/Exclusion criteria**Inclusion criteria:**

1. Aged 18-35 years 2. Lean adult include: with a BMI of 18.5-23.5 kg/m², body fat percent between 12-22%, waist circumference <90cm; obese adult include: with a BMI>27.5 kg/m², body fat percent > 27%, waist circumference >90cm. 3. Men 4. Signing the Written informed consent 5. willing to undertake required fasting durations

Exclusion criteria:**Age**

From **18 years** old to **35 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of school of medicine, mashhad university of medical science

Street address

emam khomeini avenue

City

gonbad kavous

Province

Golestan

Postal code

4969154635

Approval date

2019-05-28, 1398/03/07

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.185

Health conditions studied**1****Description of health condition studied**

lean and obese men

ICD-10 code

e65-e68

ICD-10 code description

e66.0

Primary outcomes**1****Description**

respiratory quotient

Timepoint

during 6 hours after test meal(half hours after meal and thus every 1hours until 6 hours)

Method of measurement

indirect calorimetry

2**Description**

resting energy expenditure

Timepoint

during 6 hours after test meal(half hours after meal and thus every 1hours until 6 hours)

Method of measurement

indirect calorimetry

3**Description**

total energy expenditure

Timepoint

during 6 hours after test meal(half hours after meal and thus every 1hours until 6 hours)

Method of measurement

indirect calorimetry

4**Description**

Diet induced thermogenesis

Timepoint

during 6 hours after test meal(half hours after meal and thus every 1hours until 6 hours)

Method of measurement

indirect calorimetry

Secondary outcomes

1

Description

pulse wave analysis

Timepoint

during 6 hours after test meal(half hours after meal and thus every 1hours until 6 hours)

Method of measurement

tonometry

2

Description

pulse wave velocity

Timepoint

during 6 hours after test meal(half hours after meal and thus every 1hours until 6 hours)

Method of measurement

tonometry

3

Description

blood sugar

Timepoint

during 6 hours after test meal(half hours after meal and thus every 1hours until 6 hours)

Method of measurement

blood sample

4

Description

insulin

Timepoint

during 6 hours after test meal(half hours after meal and thus every 1hours until 6 hours)

Method of measurement

blood sample

5

Description

lipid profile

Timepoint

during 6 hours after test meal(half hours after meal and thus every 1hours until 6 hours)

Method of measurement

blood sample

Intervention groups

1

Description

Intervention group: obese men that will receive three test meal in three days such as high protein, high fat and high protein. they will evaluate during 6hours

Category

Other

2

Description

Intervention group: lean men that will receive three test meal in three days such as high protein, high fat and high protein. they will evaluate during 6hours

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

imam reza hospital

Full name of responsible person

mohammad safarian

Street address

daneshgah avenue

City

mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Phone

+98 51 3859 8477

Email

safarianm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

mohammad sfarian

Street address

daneshgah

City

mashhad

Province

Razavi Khorasan

Postal code

9137673119

Phone

+98 51 3859 8477

Email

safarianm@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

90

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

safieh firouzi

Position

ph.d student

Latest degree

Master

Other areas of specialty/work

Nutrition

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vakilabad

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Email

firouzis951@mums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

safieh firouzi

Position

ph.d student

Latest degree

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Other areas of specialty/work

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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)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

individually nonidentifiable of participants will be shared in this study. also, the protocol, results and statistical analysis of the study will be published in the relevant articles.

When the data will become available and for how long

unidentifiable personal information of the participants will be available after publication of the related articles.

To whom data/document is available

unidentifiable personal information of the participants will be made available after to other researchers at academic institutions

Under which criteria data/document could be used

unidentifiable personal information of the participants can only be used for research

From where data/document is obtainable

individually nonidentifiable information of participants can be obtained by sending an email to Dr mohammad safarian(safarianm@mums.ac.ir)

What processes are involved for a request to access data/document

other researchers in academic institutions can send their request by email to dr. mohammad safarian. the data will be sent to them after consulting and approving the research team.

Comments