

# 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/m<sup>2</sup>, body fat percent between 12-22%, waist circumference <90cm; obese adult include: with a BMI>27.5 kg/m<sup>2</sup>, 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/m<sup>2</sup>, body fat percent between 12-22%, waist circumference <90cm; obese adult include: with a BMI>27.5 kg/m<sup>2</sup>, 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

**Street address**

vakilabad

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

91388-13944

**Phone**

+98 51 3800 2423

**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**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

vakilabad

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**Person responsible for updating data****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

**Street address**

vakilabad

**City**

mashhad

**Province**

Razavi Khorasan

**Postal code**

91388-13944

**Phone**

+98 51 3800 2423

**Email**

firouzis951@mums.ac.ir

**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**