Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Oct 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 caffein. 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, charbohydrate 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
Street address
vakilabad
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Person responsible for scientific inquiries

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Person responsible for updating data

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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