

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the acute effect of Traditional Persian medicine based hot and cold foods on Metabolic Responses and Arterial Stiffness in healthy men

Protocol summary

Study aim

Examination of the effect of Traditional Persian medicine based hot and cold foods on metabolic responses and arterial stiffness indexes during postprandial phase in adult males with hot and cold temperaments

Design

crossover clinical trial

Settings and conduct

Imam Reza Hospital

Participants/Inclusion and exclusion criteria

a BMI of 18.5-25 kg/m², body fat percent between 12-22%, waist circumference <90cm aged 20-25 years Men Signing the Written informed consent willing to undertake required fasting durations

Intervention groups

Intervention group: men with hot and cold temperament that will receive two test meals in 2 days including Traditional based medicine hot and cold food. they will evaluate during 4hours

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

HCFMR

IRCT registration information

IRCT registration number: **IRCT20200417047105N1**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-19, 1399/01/31**

Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Mohsen Zakerian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2423

Email address

zakerianmohsen@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the acute effect of Traditional Persian medicine based hot and cold foods on Metabolic Responses and Arterial Stiffness in healthy men

Public title

Traditional Persian medicine based hot and cold foods and Metabolic Responses and Arterial Stiffness

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

a BMI of 18.5-25 kg/m², body fat percent between 12-22%, waist circumference <90cm aged 20-25 years
Men Signing the Written informed consent willing to undertake required fasting durations

Exclusion criteria:

Use of supplement for weight loss and weight gain
Professional athlete who cannot consume test meals due to intolerances/dietary preferences (i.e. vegan, gluten, milk proteins) change in body weight greater than 10% in 6 months past Current smoking use of medications that might affect study outcomes such as hypo and hyper thyroid and caffeine 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

Age

From **20 years** old to **25 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 Mashhad University of Medical Sciences

Street address

Campus of University (Paradise Daneshgah), Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

91779-48564

Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.MUMS.REC.1398.014

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

Men with Traditional Persian Medicine based hot and cold temperaments

ICD-10 code

E88.9

ICD-10 code description

Metabolic disorder, unspecified

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

respiratory quotient

Timepoint

during 4 hours after test meal(half hours after meal and thus every 2 hours until 4 hours)

Method of measurement

Indirect calorimetry

2**Description**

resting energy expenditure

Timepoint

during 4 hours after test meal(half hours after meal and thus every 2 hours until 4 hours)

Method of measurement

Indirect calorimetry

3**Description**

total energy expenditure

Timepoint

during 4 hours after test meal(half hours after meal and thus every 2 hours until 4 hours)

Method of measurement

Indirect calorimetry

4**Description**

Diet induced thermogenesis

Timepoint

during 4 hours after test meal(half hours after meal and thus every 2 hours until 4 hours)

Method of measurement

Indirect calorimetry

Secondary outcomes

1

Description

pulse wave analysis

Timepoint

during 4 hours after test meal(half hours after meal and thus every 2hours until 4 hours)

Method of measurement

Tonometry

2

Description

pulse wave velocity

Timepoint

during 4 hours after test meal(half hours after meal and thus every 2hours until 4 hours)

Method of measurement

Tonometry

3

Description

blood sugar

Timepoint

during 4 hours after test meal(half hours after meal and thus every 2hours until 4 hours)

Method of measurement

blood sample

4

Description

Insulin

Timepoint

during 4 hours after test meal(half hours after meal and thus every 2hours until 4 hours)

Method of measurement

blood sample

5

Description

Lipid profile

Timepoint

during 4 hours after test meal(half hours after meal and thus every 2hours until 4 hours)

Method of measurement

blood sample

Intervention groups

1

Description

Intervention group: men with hot temperament that will receive two test meals in 2 days including Traditional based medicine hot and cold food. they will evaluate during 4hours

Category

Other

2

Description

Intervention group: Intervention group: men with cold temperament that will receive two test meals in 2 days including Traditional based medicine hot and cold food. they will evaluate during 4hours

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Maliheh Motavasselian

Street address

Mashhad University of Medical Sciences (MUMS)
Campus of University (Paradise Daneshgah), Azadi Square

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Email

MotavasselianM@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

Deputy of Research and Technology of the University,
Qoreishi Center, Daneshgah street.

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Mashhad

Province

South Khorasan

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13131 - 99137

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+98 51 3841 1538

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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
Mohsen Zakerian
Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Persian Medicine
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The non-identifiable individual participant data collected in this study will be shared. Also, The protocol, results, and statistical analysis of the current study will be published in the relevant articles.
When the data will become available and for how long
The non-identifiable individual participant data will become available after the publication of the relevant

articles.

To whom data/document is available

they will be available for people working in academic institutions and people working in businesses can also apply to receive it.

Under which criteria data/document could be used

The non-identifiable individual participant data can only be used for research.

From where data/document is obtainable

The non-identifiable individual participant data will be

obtainable by sending an e-mail to Mohsen Zakerian (Zakerianmohsen@gmail.com)

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

Other researchers in academic institutions can send their request by e-mail to Mohsen Zakarian. The data will be sent to them after consulting and approving the research team.

Comments