Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

To assess the effects of coconut oil consumption on metabolic syndrome indices in adults

Protocol summary

Study aim
Determination of the Effects of Coconut Oil on Metabolic Syndrome Indices in Adults

Design
A randomized, controlled, clinical, parallel trial (with a 22-person coconut oil group and a control group (44 patients in total)).

Settings and conduct
Forty-five men and women between the ages of 20 and 50 with metabolic syndrome will be selected based on NCEP ATP III criteria from persons have come to the Tehran Heart Center. Anthropometric assessments and body composition and blood pressure are measured and a demographic questionnaire is completed. and 3 days recall will be taken from the patients. Blood will be taken from patients for biochemical tests (lipid profile, serum glucose, ALT, AST and asymmetric dimethyl arginine), all of which will be administered again after 4 weeks of Consumption of coconut oil 30 ml daily by coconut oil group , for both groups.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Men and women between the ages of 20 and 50 with a diagnosis of metabolic syndrome who are willing to participate in the study. • Exclusion criteria: History of any type of medical or surgical disease, alcohol consumption, history of intolerance to coconut oil, pregnancy or breastfeeding, smoking or any type of industrial and traditional drug use, consumption Any drug or dietary supplement that affects metabolic syndrome indices, To follow any particular diet or weight loss program, changes in the last three months, and professional exercise

Intervention groups
1.The group taking coconut oil 2. Control group (receiving their usual consumption of oil)

Main outcome variables
blood pressure , Waist circumference, Serum lipid profile, Serum glucose, serum Asymmetric dimethyl arginine

General information

Reason for update
Adding and evaluating new variables was considered due to receiving more financial resources and in line with the registered trial.

Acronym

IRCT registration information
IRCT registration number: **IRCT20131125015536N11**
Registration date: **2020-01-10, 1398/10/20**
Registration timing: **retrospective**

Last update: **2021-04-19, 1400/01/30**
Update count: **1**

Registration date
2020-01-10, 1398/10/20

Registrant information

Name
Mohammad Javad Hosseinzadeh
Name of organization / entity
School of Nutritional Sciences and Dietetics, TUMS
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-22, 1398/04/31

Expected recruitment end date
2019-12-21, 1398/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
To assess the effects of coconut oil consumption on metabolic syndrome indices in adults

Public title
The effects of coconut oil in metabolic syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
20 to 50 years old men and women diagnosed as metabolic syndrome Giving informed consent for participation in the study
Exclusion criteria:
The history of any type of medical or surgical disease, drinking alcohol, history of coconut oil intolerance, pregnancy or breastfeeding, smoking or any type of drug, the use of any drug or supplement that affects metabolic syndrome indices. , Compliance with a particular diet or weight loss program, changes in the last three months and professional exercise, a patient's unwillingness to continue to study, hypersensitivity or intolerance to the consumption of coconut oil
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to receive coconut oil and control group. The randomized assignment of patients to the two groups will be utilized by a Stratified blocked randomization.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Sixth Floor, Central Organization of Tehran University of Medical Sciences, Qods St, Keshavarz Blvd,Tehran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2019-06-10, 1398/03/20
Ethics committee reference number
IR.TUMS.VCR.REC.1398.242

Health conditions studied

1

Description of health condition studied
metabolic syndrome
ICD-10 code
E88.81
ICD-10 code description
metabolic syndrome

Primary outcomes

1

Description
Blood pressure
Timepoint
Before and after 4 weeks of intervention
Method of measurement
Digital barometer

2

Description
serum Fasting blood glucose level
Timepoint
Before and after 4 weeks of intervention
Method of measurement
Enzymatic Kit

3

Description
serum triglyceride level
Timepoint
Before and after 4 weeks of intervention
Method of measurement
Enzymatic Kit

4

Description
serum HDL-C level
Timepoint
Before and after 4 weeks of intervention

Method of measurement
Enzymatic Kit

5

Description
serum Asymmetric D-methyl arginine level
Timepoint
Before and after 4 weeks of intervention
Method of measurement
Eliza kit

6

Description
Waist circumference
Timepoint
Before and after 4 weeks of intervention
Method of measurement
observation

7

Description
serum brain derived neurotrophic factor level
Timepoint
Before and after 4 weeks of intervention
Method of measurement
Eliza kit

Secondary outcomes

1

Description
Body composition analysis
Timepoint
Before and after 4 weeks of intervention
Method of measurement
Bio-electrical impedance analysis

2

Description
Serum lipid profile
Timepoint
Before and after 4 weeks of intervention
Method of measurement
Enzymatic Kit

3

Description
Serum insulin level
Timepoint
Before and after 4 weeks of intervention
Method of measurement
Eliza kit

4

Description
serum malondialdehyde level
Timepoint
Before and after 4 weeks of intervention
Method of measurement
MDA assay Kit (colorimetrically or fluorometrically)

5

Description
serum total antioxidant capacity
Timepoint
Before and after 4 weeks of intervention
Method of measurement
TAC assay Kit (photometrically)

Intervention groups

1

Description
Intervention group: Daily intake of 30 ml of coconut oil in the preparation of food or cold as an alternative to the portion of the oil intake
Category
Treatment - Other

2

Description
Control group: People in this group will continue to receive their usual diet, especially in terms of type and amount of oil consumed.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran heart center hospital
Full name of responsible person
Ali vasheghani farahani
Street address
North Kargar-Ave, Jalal Al Ahmad Highway, Tehran-Iran
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammad Ali Sahraian

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Sixth floor, Central Organization of Tehran University of Medical Sciences, Ghods St, Keshavarz Blvd, Tehran

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msahrai@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
parinaz nikooei

Position
M.Sc Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

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No: 44, Hojjat-dost Alley, Naderi St., Keshavarz Blvd, Tehran, Iran

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Person responsible for scientific inquiries

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Name of organization / entity
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Mohammad-Javad Hosseinzadeh-Attar

Position
MD, PhD, Professor

Latest degree
Ph.D.

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Nutrition

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Position
M.Sc Student

Latest degree
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Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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