

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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

Country

Iran (Islamic Republic of)

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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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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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Name of organization / entity

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Full name of responsible person

Mohammad-Javad Hosseinzadeh-Attar

Position

MD, PhD, Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

parinaz nikooei

Position

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Latest degree

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Other areas of specialty/work

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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