Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Assessement of the effects of coffee main constituents (caffeine and chlorogenic acid) supplementation on inflammatory, metabolic factors, hepatic steatosis and fibrosis in none- alcoholic fatty liver patients with type 2 diabetes

Protocol summary

Summary

In this randomized, double blind, placebo controlled trial with parallel design, 100 patients suffering from NAFLD and type 2 diabetes will be selected among patients referring to Gastroenterology and endocrinology Clinic of Shariati Hospital in Tehran. Participants will be randomly assigned to one of the following interventions or control group based on the blocked randomization method.In this study neither the patient nor the clinical and laboratory investigators will be aware of the treatment assignment. 1) Group I: will receive caffeine (200 mg) 1 capsule/d plus chlorogenic acid (200 mg) 1 capsule/d for 6 months. 2) Group II: will receive caffeine (200 mg) 1 capsule/d plus placebo (200 mg) 1 capsule/d for 6 months. 3) Group III: will receive placebo (200 mg) 1 capsule/d plus chlorogenic acid (200 mg) 1 capsule/d for 6 months. 4) Group IV: will receive placebo (200 mg) 1 capsule/d plus placebo (200 mg) 1 capsule/d for 6 months. So supplementation will be daily and will supervise for 6 months. After a 10- to 12-h fasting, blood samples will be taken at baseline and at 6th month of the intervention. Fatty liver will be diagnosed by documented laboratory data and FibroScan. The initial clinical visit will be 2 weeks after the introduction of treatment in arms. The follow-up interval will be every 4 weeks. Measurements will be taken on the day treatment begins (day 0) and 6 months after the treatment begins (day 180), including laboratory examinations (liver function tests (aspartate aminotransferase [AST], alanine aminotransferase [ALT]), lipid profile, blood glucose, inflammatory and oxidative stress biomarkers, and insulin resistance) and body composition, blood pressure, hepatic steatosis and fibrosis, anthropometric measurement, and self-administered questionnaires to evaluate subjective symptoms, lifestyle factors, menopausal status and postmenopausal, and medication use). Compliance with treatment will be assessed at each visit (monthly) by interview. To assess potential changes in daily food consumption and physical activity during the 6-month intervention, participants will keep a completely food intake record for a 72-h period at home and a record of their physical activity at baseline and at 6th month of the intervention. All participants will be advised a balanced diet for the duration of trial.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201707024010N21**
Registration date: **2017-09-15, 1396/06/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-15, 1396/06/24

Registrant information

Name
Azita Hekmatdoost
Name of organization / entity
Shahid Beheshti University of Medical Sciences, National Institute of Nutrition Research
Country
Iran (Islamic Republic of)
Phone
+98 21 2293 0824
Email address
hekmat@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

NNFTRI, SBMU

Expected recruitment start date
2017-10-02, 1396/07/10
Expected recruitment end date
2018-10-02, 1397/07/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessement of the effects of coffee main constituents (caffeine and chlorogenic acid) supplementation on inflammatory, metabolic factors, hepatic steatosis and fibrosis in none- alcoholic fatty liver patients with type 2 diabetes

Public title
Assessement of the effects of coffee main constituents in none- alcoholic fatty liver patients with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Patient diagnosed with type 2 diabetes based on American Diabetes Association (ADA) definition or who only take oral antidiabetic drug. CAPscore >263 Exclusion Criteria: Taking any kind of antibiotics two weeks before recruitment; History of alcohol consumption ; pregnancy or lactation; Professional athletes; Other liver disease (viral/etc); High dose synthetic estrogens, methotrexate , amiodarone, steroids, chloroquine, immunosuppressive drugs; A history of Cardiovascular disease; Renal disease, Celiac disease, Cirrhosis; History of Upper Gastrointestinal surgery ; A history of hypothyroidism or Cushing's syndrome; History of drug dependence; Body mass index (BMI) ≥35 kg/m2; A restrictive diet or weight change ≥ 5 kg during the 3 months prior to study; Any change in treatment with oral hypoglycemic; anti hypertensive and antilipid agents during the study; Use of weight loss medications
Age
From **30 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
NNFTRI, SBMU
Street address
46, Hafezi St., Farahzadi Blvd., Shahrak QODS, Tehran, Iran
City
Tehran
Postal code
Approval date
2017-07-18, 1396/04/27
Ethics committee reference number
1396.145

Health conditions studied

1

Description of health condition studied
NAFLD
ICD-10 code
k76.0
ICD-10 code description
(Nonalcoholic fatty liver disease (NAFLD

Primary outcomes

1

Description
ALT
Timepoint
Before and 24 weekes after the intervention
Method of measurement
U/L

2

Description
Liver Steatosis
Timepoint
Before and 6 weekes after the intervention
Method of measurement
ultrasonography

3

Description
Liver fibrosis
Timepoint

Before and 24 weekes after the intervention

Method of measurement

fiberscan

4

Description

glucose

Timepoint

Before and 24 weekes after the intervention

Method of measurement

mg/dl

5

Description

weight

Timepoint

Before and 24 weekes after the intervention

Method of measurement

kg

6

Description

AST

Timepoint

Before and 24 weekes after the intervention

Method of measurement

U/L

7

Description

GGT

Timepoint

Before and 24 weekes after the intervention

Method of measurement

U/L

Secondary outcomes

1

Description

TG

Timepoint

Before and 24 weekes after the intervention

Method of measurement

mg/dl

2

Description

TC

Timepoint

Before and 24 weekes after the intervention

Method of measurement

mg/dl

3

Description

LDL-C

Timepoint

Before and 24 weekes after the intervention

Method of measurement

mg/dl

4

Description

HDL-C

Timepoint

Before and 24 weekes after the intervention

Method of measurement

mg/dl

5

Description

TNF-α

Timepoint

Before and 24 weekes after the intervention

Method of measurement

pg/ml

6

Description

Insulin

Timepoint

Before and 24 weekes after the intervention

Method of measurement

μU/mL

7

Description

c-peptide

Timepoint

Before and 24 weekes after the intervention

Method of measurement

ng /ml

8

Description

CRP

Timepoint

Before and 24 weekes after the intervention

Method of measurement

mg/l

9

Description

HbA1C

Timepoint

Before and 24 weekes after the intervention

Method of measurement

%

10

Description

TAC

Timepoint
Before and 24 weekes after the intervention
Method of measurement
µg/l

11

Description
Cytokeratin 18
Timepoint
Before and 24 weekes after the intervention
Method of measurement
u/l

12

Description
NFK-B
Timepoint
Before and 24 weekes after the intervention
Method of measurement
-

13

Description
α2-Macroglobulin
Timepoint
Before and 24 weekes after the intervention
Method of measurement
mg/l

14

Description
Adiponectin
Timepoint
Before and 24 weekes after the intervention
Method of measurement
µg/ml

15

Description
leptin
Timepoint
Before and 24 weekes after the intervention
Method of measurement
ng /ml

16

Description
IFN-g
Timepoint
Before and 24 weekes after the intervention
Method of measurement
pg/ml

Intervention groups

1

Description
caffeine (200 mg) 1 capsule/d plus placebo (200 mg) 1 capsule/d
Category
Treatment - Other

2

Description
placebo (200 mg) 1 capsule/d plus chlorogenic acid (200 mg) 1 capsule/
Category
Treatment - Other

3

Description
caffeine (200 mg) 1 capsule/d plus chlorogenic acid (200 mg) 1 capsule/d
Category
Treatment - Other

4

Description
placebo (200 mg) 1 capsule/d plus placebo (200 mg) 1 capsule/d
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology & Metabolism Institue,Tehran University of Medical Sciences
Full name of responsible person
Mohammad Reza Mohajeri- Tehrani
Street address
Endocrinology & Metabolism Research Institute, 5th floor, Shariati Hospital, North Kargar Avenue, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
NIMAD
Full name of responsible person
Azita Hekmatdoost
Street address
21, Besat St, west fatemi Ave, Tehran, IRAN
City
Tehran
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
NIMAD
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor
Name of organization / entity
DDRI
Full name of responsible person
Azita Hekmatdoost
Street address
Shariati Hospital,North Kargar Ave
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
DDRI
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Faculty of Nutrition and Food Technology, Shahid Beheshti University of Medical Science
Full name of responsible person
Asieh Mansour
Position
PhD student in nutrition
Other areas of specialty/work
Street address
46, Hafezi St., Farahzadi Blvd., Shahrak QODS, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 8822 0071
Fax
Email
asiehmansour@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nutrition and Food Technology, Shahid Beheshti University of Medical Science
Full name of responsible person
Azita Hekmatdoost
Position
MD-PhD in nutrition
Other areas of specialty/work
Street address
46, Hafezi St., Farahzadi Blvd., Shahrak QODS, Tehran, Iran
City
Tehran
Postal code
Phone
+98 21 2235 7483
Fax
Email
a_hekmat2000@yahoo.com
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty