

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effects of green cardamom (*Elettaria Cardamomum*) supplementation along with lifestyle changes on blood glucose index, lipids, inflammation factors, paraxonase-1, sirtuin-1 and irisin in overweight and obese patients with non-alcoholic fatty liver disease (NAFLD)

Protocol summary

Summary

This study as a double-blind randomized controlled clinical trial aimed to determine the effects of green cardamom supplementation along with lifestyle changes on blood glucose index, lipids, inflammation factors, paraxonase-1, sirtuin-1 and irisin in overweight and obese patients with non-alcoholic fatty liver disease (NAFLD). Totally 80 patients are invited based on inclusion and exclusion criteria. Weight, height and blood pressure are recorded using a digital scale, stadiometer and mercury barometer, respectively. Patients are randomly divided into two groups of 40 people, including placebo and green cardamom supplementation for three months groups. Green cardamom and placebo (flour breadcrumbs) standardized supplements are prepared as 1 gram capsules. One capsule per meal should be consumed. At beginning, lifestyle changes advises including low-caloric diet and regular physical activity will be prescribed. A 24-hr recall questionnaire is completed in baseline, after 1.5 months and end of study. Physical activity and fatty liver degree are assessed using short-form IPAQ (International Physical Activity Questionnaire) and ultrasonography, respectively, before and after the intervention. Also, 10 ml of blood from the brachial vein of patients are taken to measurement of serum factors at the beginning and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121317254N4**

Registration date: **2015-12-27, 1394/10/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-27, 1394/10/06

Registrant information

Name

Gity Sotoude

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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gsotodeh@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-05-09, 1395/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of green cardamom (*Elettaria Cardamomum*) supplementation along with lifestyle changes on blood glucose index, lipids, inflammation factors, paraxonase-1, sirtuin-1 and irisin in overweight and obese patients with non-alcoholic fatty liver disease

(NAFLD)

Public title

Effect of green cardamom on improvement of non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: non-alcoholic fatty liver disease diagnosed by a radiologist and hepatologist using ultrasonography into one of three categories (mild, moderate or severe degree); age 30-60 years old; overweight or obesity ($25 \leq \text{BMI} < 35$); informed consent signed and dated by the subject and investigator. Exclusion criteria: history of alcohol consumption at the time of the study or in the past 12 months, based on patient confession; diagnosed pathological conditions affecting the liver such as viral hepatitis, acute or chronic liver failure, cholestasis, liver transplantation, habitual abuse of nonsteroidal anti-inflammatory drugs, antibiotics, anti-secretory drugs cause achlorhydria within 3 months before the study, Corticosteroids, amiodarone, valproate, prednisone, tamoxifen, perhexiline and methotrexate, rapid weight loss, diabetes, heart failure, thyroid disorders, kidney disease, respiratory failure, psychological disorders, hereditary hemochromatosis and Wilson disease, alpha-1 antitrypsin deficiency, autoimmune diseases, celiac disease, use of liver fat inducer and hormonal drugs; acute systemic disease, cystic fibrosis disease, muscular dystrophy, protein malnutrition, history of gastrointestinal surgery, neurological disorders, structural abnormalities of the gastrointestinal tract; the secondary causes of NAFLD, including drugs, surgical procedures, environmental toxins and total parenteral nutrition (TPN); conditions lead to the physical inactivity (disability); uncontrolled hypertension ($>90/140$ mmHg); any diagnosed malignancy; breast-feeding, pregnancy and or plan for pregnancy in the next 3 months; professional athlete or regular exercise; treatment with statins, antihypertensive and ursodeoxy colic acid, probiotics and multivitamin-mineral and antioxidant supplements during the three months prior to the intervention; surgery for weight loss in the last year and weight loss program for the past three month; different drugs that interact with cardamom, including aspirin, anticoagulants (warfarin, heparin) and antiplatelet (clopidogrel), non-steroidal anti-inflammatory (ibuprofen or naproxen), blood pressure-lowering drugs, CNS depressants (benzodiazepines such as lorazepam or diazepam, barbiturates such as phenobarbital, narcotics such as codeine, some antidepressants and alcohol), anesthetics, antibiotics, anti-cancer agents, anti-cholinergics, anti-fungals, cyproheptadine, diuretics (loop), estrogen, indomethacin, muscarinic agents, pain relievers and prednisolone; taking a multivitamin-mineral and or antioxidants supplement at least twice a week during study; not taking more than 10% of prescription supplements.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Tehran University of Medical Sciences

Street address

Keshavarz Beulvard, First of Qods

City

Tehran

Postal code**Approval date**

2015-09-20, 1394/06/29

Ethics committee reference number

IR.TUMS.REC.1394.791

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

Nonalcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Nonalcoholic fatty liver disease

2**Description of health condition studied**

Overweight or Obesity

ICD-10 code

E66

ICD-10 code description

overweight or obesity

Primary outcomes

1

Description

Serum Irisin

Timepoint

Before and after intervention

Method of measurement

Elisa kit

2

Description

Serum Sirtuin1

Timepoint

Before and after intervention

Method of measurement

Elisa kit

3

Description

Serum Paraxonase-1

Timepoint

Before and after intervention

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Serum TNF-a, IL-6 and hs-CRP

Timepoint

Before and after intervention

Method of measurement

Elisa Kit

2

Description

FBS, FPI

Timepoint

Before and after intervention

Method of measurement

Kit

3

Description

SBP, DBP

Timepoint

Before and after intervention

Method of measurement

mmhg by mercury manometer

4

Description

Serum TG, TC, LDL and HDL

Timepoint

Before and after intervention

Method of measurement

Kit

Intervention groups

1

Description

Green cardamom supplementation, 3 gram/day, 3 capsules (1gram)/day with food, for 3 months

Category

Treatment - Other

2

Description

Placebo (bread crumbs) supplementation, 3 gram/day, 3 capsules (1gram)/day with food, for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Oil Company Hospital of Tehran

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mrs. Rostamabadi

Street address

Keshavarz Beulvard, First of Qods St

City

Tehran

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

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

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Full name of responsible person

Gity Sotoudeh

Position

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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