Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Oct 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

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Tehran University of Medical Sciences
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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-alcohilic 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; overwight or obesity (25≤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

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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