Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The clinical trial of effects of nanocurcumin supplementation on blood nesfatin, insulin resistance indexes, lipids and inflammatory factors in overweight and obese patients with non-alcoholic fatty liver disease (NAFLD)

Protocol summary

Summary

This study as a double-blind randomised controlled trial will be conducted in 84 overweight or obese patients with non-alcoholic fatty liver. Disease is diagnosed using ultrasonography by a radiologists. Patients are divided into nanocurcumin and placebo supplementation equal groups (ratio 1:1). The period of study is considered three months. Two 40mg capsules (nanocurcumin or placebo) will be included daily with breakfast and dinner meals. Advises of lifestyle changes include low-calorie diet and increasing physical activity. Food intakes, physical activity, weight, height, blood pressure and body composition of patients are measured at different visits. At the beginning and end of the study 10 ml blood from the brachial vein of patients will be taken to measure serum levels of liver enzymes (Alanin transaminase (ALT), Aspartate transaminase (AST)), fasting glucose (FBS) and insulin (FBI)), Hemoglobin A1C (HbA1C), lipid profile (Low Density Lipoprotein-Cholestrol (LDL) , High Density Lipoprotein-Cholestrol (HDL), Triglyceride (TG), Total Cholestrol (TC)), Interleukin-6 (IL-6), Tumor Necrosis Factor-alpha (TNF-α), high sensitive-C-Reactive Protein (hs-CRP) and nesfatin. Also, insulin indexes (Homeostatic model assessment-insulin resistance (HOMA-IR), Quantitative insulin sensitivity check index (QUICKI)) are calculated by the following formula: QUICKI = 1 / (log (fasting insulin μU / mL) + log (fasting glucose mg / dL)) HOMA-IR = (FPI (mU / l) x FPG (mmol / l)) / 22.5

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071915536N3**

Registration date: **2016-08-02, 1395/05/12**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-02, 1395/05/12

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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+98 21 8899 3059

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The clinical trial of effects of nanocurcumin

supplementation on blood nesfatin, insulin resistance indexes, lipids and inflammatory factors in overweight and obese patients with non-alcoholic fatty liver disease (NAFLD)

Public title
Effects of nanocurcumin in the treatment 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 25–50 years; Overwight or obesity (25≤BMI<35). 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; Taking a multivitamin-mineral and or antioxidants supplement at least once a week during the study; Not taking more than 10% of prescription supplements
Age
From **25 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
No.1, Qods Ave, Keshavarz Blvd, Tehran
City
Tehran
Postal code
Approval date
2016-05-17, 1395/02/28
Ethics committee reference number
IR.TUMS.REC.1395.2612

Health conditions studied

1

Description of health condition studied
Non alcoholic fatty liver disease
ICD-10 code
K75.8, K76
ICD-10 code description
Nonalcoholic steatohepatitis, Nonalcoholic fatty liver disease

Primary outcomes

1

Description
Nesfatin
Timepoint
At the beginning and end of intervention
Method of measurement
serum levels (ng/ml) by Elisa

Secondary outcomes

1

Description

ALT/AST/TG/TC/HDL/LDL/FBS/FBI/HbA1C/TNF-Alpha/IL-6/hs-CRP

Timepoint

At the beginning and end of intervention

Method of measurement

Serum levels by Elisa

2

Description

Blood pressure, Body composition, Body Mass Iindex, Waist Circumference

Timepoint

At the beginning and end of intervention

Method of measurement

Mercury manometer, BIA, Formula, Tape measure (mmhg, %, kg/m2, cm), respectively

Intervention groups

1

Description

Intervention Group: Nanocurcumin supplementation with dose of 80mg (40mg bid with breakfast and dinner meals) for 3 months.

Category

Treatment - Other

2

Description

Placebo Group: Placebo supplementation with dose of 80mg (40mg bid with breakfast and dinner meals) for 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital of Oil Company

Full name of responsible person

Siavash Mansouri

Street address

No.11, Sakhaei Ave, Hafez St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Mohammad-Javad Hosseinzadeh-Attar

Street address

No.44, Hojjatdoust Alley, Naderi St, Keshavarz Blvd, Tehran.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, 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

School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences

Full name of responsible person

Mohammad-Javad Hosseinzadeh-Attar

Position

MD, PhD, Associate Professor

Other areas of specialty/work

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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