

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 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-Cholesterol (LDL) , High Density Lipoprotein-Cholesterol (HDL), Triglyceride (TG), Total Cholesterol (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: $QUICKI = 1 / (\log(\text{fasting insulin } \mu\text{U} / \text{mL}) + \log(\text{fasting glucose mg} / \text{dL}))$ $HOMA-IR = (FPI (\text{mU} / \text{l}) \times FPG (\text{mmol} / \text{l})) / 22.5$

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)		Randomization description	
Public title		Blinding (investigator's opinion)	
Effects of nanocurcumin in the treatment of non-alcoholic fatty liver disease		Double blinded	
Purpose		Blinding description	
Treatment		Placebo	
Inclusion/Exclusion criteria		Used	
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 25–50 years; Overweight or obesity ($25 \leq \text{BMI} < 35$). 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		Assignment	
Age		Parallel	
From 25 years old to 50 years old		Other design features	
Gender		Block randomization	
Both		Secondary Ids	
Phase		empty	
N/A		Ethics committees	
Groups that have been masked		<u>1</u>	
No information		Ethics committee	
Sample size		Name of ethics committee	
Target sample size: 84		Ethics committee of Tehran University of Medical Sciences	
Randomization (investigator's opinion)		Street address	
Randomized		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	
		<u>1</u>	
		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	
		<u>1</u>	
		Description	
		Nesfatin	
		Timepoint	
		At the beginning and end of intervention	
		Method of measurement	
		serum levels (ng/ml) by Elisa	
		Secondary outcomes	
		<u>1</u>	
		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 Index,
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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Tehran

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