Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

The effect of curcumin supplementation on lipid profile, liver enzymes, inflammatory factors and hepatic steatosis in patients with Nonalcoholic Fatty Liver Disease

Protocol summary

Study aim

The effect of curcumin supplementation on serum lipids, liver enzymes, inflammatory markers and hepatic steatosis in patients with nonalcoholic fatty liver.

Design

Randomized, double-blind, placebo-controlled

Settings and conduct

In this study, patients with non-alcoholic fatty liver reffering to Taleqani Hospital, if they wish to participate in the study informed consent of them will be taken. After 12 to 14 hours of fasting, 5 cc of blood is taken to measure their blood serum concentrations of lipids, inflammatory factors and other serum biochemical parameters and kept in the freezer. Participants randomly using the divided randomly classified into two groups: supplement and placebo group.

Participants/Inclusion and exclusion criteria

Participants including major eligibility criteria: inclusion criteria: age 18 years and above; Concentrations of liver enzymes ALT and AST greater than 1.5 times normal; Evidence of nonalcoholic steatohepatitis in Fibroscan Exclusion criteria: Not continue to cooperation; Those less than 10% supplementation at the end of the sixth and twelfth week consume.

Intervention groups

Patients group supplement will be recived daily 1.5 grams of curcumin for three months and Patients in the control group will be recived placebo daily 1.5 grams.

Main outcome variables

Low Density Lipoprotein Cholestrol (LDL-C), High Density Lipoprotein Cholestrol (HDL-C), Triglyceride(TG), Total Cholestrol, Fasting Blood Sugar(FBS), Insulin, Homeostatic Model Assessment for Insulin Resistance(HOMA-IR), Aspartate Aminotransferase(AST), Alanine Aminotransferase(ALT), TNF-α, hs-CRRP, IL-6, Liver Steatosis, Age, Sex, Smoking, Weight, Height, Waist Circumference, Hip Circumference, Waist to Hip Ratio(WHR), Body Mass Index(BMI), Total energy intake, Total carbohydrate intake, Total fat intake, Total protein intake, Total fiber intake, Total SFA intake, Total MUFA intake, Total PUFA intake

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N24**
Registration date: **2018-05-14, 1397/02/24**
Registration timing: **retrospective**

Last update: **2018-05-14, 1397/02/24**
Update count: **0**

Registration date

2018-05-14, 1397/02/24

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

Vice Chancellor Of Research, Shahid Beheshti University Of Medical Sciences

Expected recruitment start date

2017-04-09, 1396/01/20

Expected recruitment end date

2017-08-11, 1396/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin supplementation on lipid profile, liver enzymes, inflammatory factors and hepatic steatosis in patients with Nonalcoholic Fatty Liver Disease

Public title

The effect of curcumin supplementation on Nonalcoholic Fatty Liver Disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age >18 years old Controlled Attenuation Parameter (CAP score)>263 Having a history of alcohol consumption less than 10 mg per day in women and less than 20 mg per day in men Absence of other acute and chronic diseases and disorders of the liver (hepatitis B, C, etc.), biliary disease, known autoimmune diseases, cancer and inherited disorders affecting liver condition (storage disease of iron, and copper. ..) Absence of Hypertension, cardio - vascular diseases, lung disease and kidney disease, cirrhosis and celiac disease Absence of pregnancy or lactation Athletes or hospitalization Not consume medications such as metformin, vitamin E and Ursodeoxycholic Acid (UDCA) Not consume hepatotoxic drugs such as phenytoin, tamoxifen and lithium and corticosteroids and methotrexate Not consume medications of antibiotics over a week during the study period or before entering it No history of weight loss surgery in the past year the 3-month weight loss program No history of hypothyroidism, Cushing's syndrome and diabetes Lack of gall bladder disease

Exclusion criteria:

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to receive curcumin or placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method use in this study to create a randomization process is simple randomization, so we utilize random number table. Beginning of the study, in order to observe the lack of a comprehension of researcher in each group, the canisters containing the capsules are coded by a person other than the researcher to A and B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Shahid Beheshti University Of Medical Sciences

Street address

Velenjak St. , Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2017-03-06, 1395/12/16

Ethics committee reference number

IR.SBMU.nnftri.13950106

Health conditions studied

1

Description of health condition studied

Nonalcoholic Fatty Liver Disease

ICD-10 code

(K75.8)

ICD-10 code description

Other specified inflammatory liver diseases

Primary outcomes

1

Description

Type of supplement

Timepoint

Begining and end of the study

Method of measurement

Data collection forms

2

Description
LDL-C
Timepoint
Begining and end of the study
Method of measurement
Enzymatic method using a kit

3

Description
HDL-C
Timepoint
Begining and end of the study
Method of measurement
Enzymatic method using a kit

4

Description
TG
Timepoint
Begining and end of the study
Method of measurement
Enzymatic method using a kit

5

Description
Total Cholestrol
Timepoint
Begining and end of the study
Method of measurement
Enzymatic method using a kit

6

Description
AST
Timepoint
Begining and end of the study
Method of measurement
Enzymatic method using a kit

7

Description
ALT
Timepoint
Begining and end of the study
Method of measurement
Enzymatic method using a kit

8

Description
TNF-α
Timepoint
Begining and end of the study
Method of measurement
ELISA

9

Description
hs-CRP
Timepoint
Begining and end of the study
Method of measurement
ELISA

10

Description
Cytokeratin-18
Timepoint
Begining and end of the study
Method of measurement
ELISA

11

Description
IL-6
Timepoint
Begining and end of the study
Method of measurement
ELISA

12

Description
Hepatic Steatosis
Timepoint
Begining and end of the study
Method of measurement
Ultrasound

Secondary outcomes

1

Description
FBS
Timepoint
Begining and end of the study
Method of measurement
Enzymatic method using a kit

2

Description
Serum Insulin
Timepoint
Begining and end of the study
Method of measurement
Radioimmunoassay

3

Description
HOMA-IR
Timepoint
Begining and end of the study
Method of measurement

Calculation

4

Description
Ferritin
Timepoint
Begining and end of the study
Method of measurement
ELISA

5

Description
Uric Acid
Timepoint
Begining and end of the study
Method of measurement
ELISA

6

Description
Age
Timepoint
Begining of the study
Method of measurement
Question

7

Description
Sex
Timepoint
begining of the study
Method of measurement
observation

8

Description
Smoking
Timepoint
Begining of the study
Method of measurement
Questionare

9

Description
Height
Timepoint
Begining of the study
Method of measurement
Meter

10

Description
Weight
Timepoint
Begining and end of the study
Method of measurement
Balance

11

Description
BMI
Timepoint
Begining and end of the study
Method of measurement
Calculation

12

Description
Total Calorie Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

13

Description
Total Carbohydrate Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

14

Description
Total Protein Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

15

Description
Total Fat Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

16

Description
Total Fiber Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

17

Description
Total MUFA Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

18

Description
Total PUFA Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

19

Description
Total SFA Intake
Timepoint
Begining and end of the study
Method of measurement
Recall Questionare

Intervention groups

1

Description
Intervention group: 1.5 gram curcumin per day for 3 months
Category
Treatment - Other

2

Description
Control group: 1.5 gram maltodextrin per day for 3 months
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleqani Hospital
Full name of responsible person
Amir Sadeghi
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Email
taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Nutrition Faculty Of Shahid Beheshti University Of Medical Science
Full name of responsible person
Azita Hekmatdoost
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hafezi Ave, Shahid Farahzadi Blvd, Shahrak Qarb
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2237 6480
Fax

Email
A_hekmat2000@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Nutrition Faculty Of Shahid Beheshti University Of Medical Science
Full name of responsible person
Azita Hekmatdoost
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hafezi Ave, Shahid Farahzadi Blvd, Shahrak Qarb
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2237 6480
Fax
Email
A_hekmat2000@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Saeede Saadati
Position
Student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd.,Qods Town
City
Tehran
Province
Tehran
Postal code
۱۹۸۱۶۱۹۵۷۳
Phone
+98 21224325609
Fax
Email
s.saadati1992@gmail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Because the participant’s informations should remain confidental.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available