Clinical Trial Protocol
Iranian Registry of Clinical Trials
02 May 2020

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 referring 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(ALT), 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
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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. No history of 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 used 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
Beginning and end of the study

Method of measurement
Data collection forms

2

Description
LDL-C

Timepoint
Beginning and end of the study

Method of measurement
Enzymatic method using a kit
<table>
<thead>
<tr>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
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</thead>
<tbody>
<tr>
<td>HDL-C</td>
<td>Beginning and end of the study</td>
<td>Enzymatic method using a kit</td>
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<tr>
<td>TG</td>
<td>Beginning and end of the study</td>
<td>Enzymatic method using a kit</td>
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<tr>
<td>Total Cholestrol</td>
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<tr>
<td>AST</td>
<td>Beginning and end of the study</td>
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<tr>
<td>ALT</td>
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<td>TNF-α</td>
<td>Beginning and end of the study</td>
<td>ELISA</td>
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<td>hs-CRP</td>
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<td>ELISA</td>
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<tr>
<td>Cytokeratin-18</td>
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<td>ELISA</td>
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<td>IL-6</td>
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<td>Hepatic Steatosis</td>
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<td>Ultrasound</td>
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<td>FBS</td>
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<td>Enzymatic method using a kit</td>
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<td>Serum Insulin</td>
<td>Beginning and end of the study</td>
<td>Radioimmunoassay</td>
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<td>HOMA-IR</td>
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<td>Calculation</td>
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<td>Ferritin</td>
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<td>ELISA</td>
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<td>Description</td>
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<td>Method of measurement</td>
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<tr>
<td>Uric Acid</td>
<td>Beginning and end of the study</td>
<td>ELISA</td>
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<td>observation</td>
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<td>Smoking</td>
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<td>Height</td>
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<td>Weight</td>
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<td>Balance</td>
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<td>BMI</td>
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<td>Total Calorie Intake</td>
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<td>Recall Questionare</td>
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<td>Total Carbohydrate Intake</td>
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<td>Total Protein Intake</td>
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<td>Total Fat Intake</td>
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<td>Total Fiber Intake</td>
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<td>Total MUFA Intake</td>
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<tr>
<td>Total PUFA Intake</td>
<td>Beginning and end of the study</td>
<td>Recall Questionare</td>
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</tbody>
</table>
Recall Questionnaire

19
Description
Total SFA Intake
Timepoint
Beginning and end of the study
Method of measurement
Recall Questionnaire

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
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1985711151
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Email
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Arabi Ave, Daneshjoo Blvd, Velenjak
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Province
Tehran
Postal code
1985717443
Phone
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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
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Latest degree
  Master
Other areas of specialty/work
  Nutrition

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  Tehran
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  ۳۷۵۹۱۶۱۸۹۱
Phone
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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 confidential.
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