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(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
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 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

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></th>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>HDL-C</td>
<td>Beginning and end of the study</td>
<td>Enzymatic method using a kit</td>
</tr>
<tr>
<td>4</td>
<td>TG</td>
<td>Beginning and end of the study</td>
<td>Enzymatic method using a kit</td>
</tr>
<tr>
<td>5</td>
<td>Total Cholesterol</td>
<td>Beginning and end of the study</td>
<td>Enzymatic method using a kit</td>
</tr>
<tr>
<td>6</td>
<td>AST</td>
<td>Beginning and end of the study</td>
<td>Enzymatic method using a kit</td>
</tr>
<tr>
<td>7</td>
<td>ALT</td>
<td>Beginning and end of the study</td>
<td>Enzymatic method using a kit</td>
</tr>
<tr>
<td>8</td>
<td>TNF-α</td>
<td>Beginning and end of the study</td>
<td>ELISA</td>
</tr>
<tr>
<td>9</td>
<td>hs-CRP</td>
<td>Beginning and end of the study</td>
<td>ELISA</td>
</tr>
<tr>
<td>10</td>
<td>Cytokeratin-18</td>
<td>Beginning and end of the study</td>
<td>ELISA</td>
</tr>
<tr>
<td>11</td>
<td>IL-6</td>
<td>Beginning and end of the study</td>
<td>ELISA</td>
</tr>
<tr>
<td>12</td>
<td>Hepatic Steatosis</td>
<td>Beginning and end of the study</td>
<td>Ultrasound</td>
</tr>
</tbody>
</table>

**Secondary outcomes**

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Timepoint</th>
<th>Method of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>FBS</td>
<td>Beginning and end of the study</td>
<td>Enzymatic method using a kit</td>
</tr>
<tr>
<td>2</td>
<td>Serum Insulin</td>
<td>Beginning and end of the study</td>
<td>Radioimmunoassay</td>
</tr>
<tr>
<td>3</td>
<td>HOMA-IR</td>
<td>Beginning and end of the study</td>
<td>Calculation</td>
</tr>
<tr>
<td>4</td>
<td>Ferritin</td>
<td>Beginning and end of the study</td>
<td></td>
</tr>
<tr>
<td>Description</td>
<td>Timepoint</td>
<td>Method of measurement</td>
<td></td>
</tr>
<tr>
<td>---------------</td>
<td>------------------------------------</td>
<td>-------------------------</td>
<td></td>
</tr>
<tr>
<td>Uric Acid</td>
<td>Beginning and end of the study</td>
<td>ELISA</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>Beginning of the study</td>
<td>Question</td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>Beginning of the study</td>
<td>Questionnaire</td>
<td></td>
</tr>
<tr>
<td>Height</td>
<td>Beginning of the study</td>
<td>Meter</td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td>Beginning and end of the study</td>
<td>Balance</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>Beginning and end of the study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Calorie Intake</td>
<td>Beginning and end of the study</td>
<td>Recall Questionnaire</td>
<td></td>
</tr>
<tr>
<td>Total Carbohydrate Intake</td>
<td>Beginning and end of the study</td>
<td>Recall Questionnaire</td>
<td></td>
</tr>
<tr>
<td>Total Protein Intake</td>
<td>Beginning and end of the study</td>
<td>Recall Questionnaire</td>
<td></td>
</tr>
<tr>
<td>Total Fat Intake</td>
<td>Beginning and end of the study</td>
<td>Recall Questionnaire</td>
<td></td>
</tr>
<tr>
<td>Total Fiber Intake</td>
<td>Beginning and end of the study</td>
<td>Recall Questionnaire</td>
<td></td>
</tr>
<tr>
<td>Total MUFA Intake</td>
<td>Beginning and end of the study</td>
<td>Recall Questionnaire</td>
<td></td>
</tr>
<tr>
<td>Total PUFA Intake</td>
<td>Beginning and end of the study</td>
<td>Recall Questionnaire</td>
<td></td>
</tr>
</tbody>
</table>
Recall Questionare

<table>
<thead>
<tr>
<th>Timepoint</th>
<th>Total SFA Intake</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beginning and end of the study</td>
<td>Recall Questionare</td>
</tr>
</tbody>
</table>

**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**
Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**
100

**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**
A_hekmat2000@yahoo.com

**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
1981719093
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 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