The effect of quercetin supplementation on liver enzymes, inflammation indices, lipid profile and body composition, accompanied by colori control in nonalcoholic fatty liver disease: A randomized, double-blind, pilot study

Protocol summary

Summary
This study aimed to evaluate the effects of quercetin supplementation on the lipid profile, liver enzymes, inflammatory markers and body composition in non alcoholic fatty liver disease. Inclusion criteria included: Failure to alcohol abuse; Body mass index equal to or greater than 25-40 Kg / m2; Lack of other acute and chronic liver diseases and disorders; No history of biliary tract disease in the past; Lack of acute heart disease, inherited disorders affecting liver condition and Exclusion criteria: Not wanting to continue working, diseases that require special treatment, Reduction of more than 10% of baseline body weight during the intervention period, not consumption of more than 10% of the supplements in any follow-up period and in general, any inconsistent with the inclusion criteria. This study will be conducted on 110 men and women with nonalcoholic fatty liver disease, in two supplement and placebo groups confirmed by ultrasound. Intervention patients, receive 500mg capsule supplement daily, morning and evening on an empty stomach, while the placebo group received placebo twice daily500mg capsule that looks like the original supplements. Anthropometric Data collection (weight, height, body mass index, etc.) and body composition analysis using the bioelectrical impedance analysis will be measured four times during the study. 10 ml of venous blood will be taken of people at the beginning and end of the study in fasting. Measuring lipid profile variables and liver enzymes by enzymatic methods and inflammatory markers such as: tumor necrosis factor alpha and c-reactive protein also will be measured using ELISA method.

General information

Acronym

IRCT registration information
IRCT registration number: IRCT2016060628299N1
Registration date: 2016-07-13, 1395/04/23
Registration timing: registered while recruiting

Last update: 0
Update count: 0
Registration date 2016-07-13, 1395/04/23
Registrant information
Name Mahboobe Hosseinikia
Name of organization / entity Kermanshah University of Medical Sciences, School of Public Health
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Recruitment status
Recruitment complete

Funding source
The cost of the project was paid entirely from the budget of Kermanshah University of Medical Sciences

Expected recruitment start date 2016-07-10, 1395/04/20
Expected recruitment end date 2016-09-22, 1395/07/01
Actual recruitment start date empty
Actual recruitment end date empty
Trial completion date empty
Scientific title
The effect of quercetin supplementation on liver enzymes, inflammation indices, lipid profile and body composition, accompanied by caloric control in nonalcoholic fatty liver disease: A randomized, double-blind, pilot study

Public title
The effect of quercetin supplementation on nonalcoholic fatty liver disease

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria include: a willingness to participate; age 18-65 years; non-alcoholic fatty liver diagnosed by ultrasonography and liver function test (Alanine transaminase and Aspartate transaminase (more than 30u/l in men and more than 20u/l in women)); Lack of alcohol abuse (taking more than 10 grams per day for women and more than 30 grams per day for men); Body mass index equal to or greater than 40Kg/M2; Lack of other acute and chronic liver disorders (hepatitis B and C, etc.); Wilson's disease; cirrhosis; no history of biliary tract disease; acute heart failure disease; renal; pulmonary; infectious diseases; diabetes; cancer; inherited disorders affecting liver condition (iron storage disease, etc.); the absence of pregnancy and lactation; disease related to thyroid disorders; No history of weight loss surgery in the past year; the absence of lose weight in the past three months and In general, lack of increase or decrease in weight regimes during the three months prior to sampling; Autoimmune diseases such as primary biliary cirrhosis, autoimmune hepatitis, sclerosing cholangitis; Non-use of antioxidant supplements during one month prior to sampling; Lack of use of effective drugs against weight during the three months prior to sampling; Do not use multivitamin-minerals and drugs that are most likely associated with this disease(Antiepileptic drugs, amiodarone, corticosteroids, phenytoin, lithium, roacutan, tamoxifen, methotrexate, aspirin, 5-fluorouracil, zidovudine, a synthetic estrogen, inhibitors of hydroxymethyl glutaryl coa reductase and etc); Lack of exposure to pesticides and insecticides such as: carbon tetrachloride; trichloroethylene; Avoiding the use of drugs that are likely to overlap with quercetin; including anticoagulants, inhibitors of CYP3A4 and ....
Exclusion criteria included: Not wanting to continue working; diseases that require special treatment; Reduction of more than 10% of baseline body weight during the intervention period; not consumption of more than 10% of the supplements in any follow-up period and in general, any inconsistent with the inclusion criteria.

Age
From 18 years old to 65 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 110

Randomization (investigator's opinion)
Randomized

Randomization description
Double blinded

Blinding (investigator's opinion)
Double blinded

Placebo
Used

Assignment
Parallel

Other design features

Secondary IDs
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Kermanshah University of Medical Sciences
Street address
Building No. 2, Shahid Beheshti Boulevard, Kermanshah
City
Kermanshah
Postal code
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
KUMS.REC.2016.79

Health conditions studied

1

Description of health condition studied
Non Alcoholic Fatty Liver Disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Lipid profile
Timepoint
at first and the end of study
Method of measurement
enzymatic method

2

Description
liver enzymes
Timepoint
at first and the end of study
### Secondary outcomes

1. **Description**
   - Body composition

   **Timepoint**
   - At first of the study and the end of forth, eighth and Twelfth weeks

   **Method of measurement**
   - BIA

2. **Description**
   - Weight

   **Timepoint**
   - At first of the study and the end of forth, eighth and Twelfth weeks

   **Method of measurement**
   - With light clothing and using Seca scales with 100 gAccuracy

3. **Description**
   - Height

   **Timepoint**
   - Accuracy

   **Method of measurement**
   - بدون کفش با استفاده از قد سنج سکا با دقت 0.1 سانتی متر

4. **Description**
   - Waist circumference

   **Timepoint**
   - At first of the study and the end of forth, eighth and Twelfth weeks

   **Method of measurement**
   - Using a tape measure between the lowest gear and iliac crest with accuracy of 0.5 cm

5. **Description**
   - Hip circumference

   **Timepoint**
   - At first of the study and the end of forth, eighth and Twelfth weeks

   **Method of measurement**
   - Using a tape measure at the biggest part of the hips

### Intervention groups

1. **Description**
   - Sigma quercetin supplements, 500 mg per day for 55 people in the intervention group for three months. Be taken on an empty stomach

   **Category**
   - Treatment - Drugs

2. **Description**
   - Placebo supplement containing starch but looks completely like the original supplementation for placebo group received 500 mg per day for 55 people for three months. Be taken on an empty stomach

   **Category**
   - Treatment - Drugs

### Recruitment centers

1. **Recruitment center**
   - **Name of recruitment center**
     - Dr. Nawabi Clinic
   - **Full name of responsible person**
     - Mahboobe Hosseibikia
   - **Street address**
     - Ejaliye Building, municipal Street, Kermanshah
   - **City**
     - Kermanshah

### Sponsors / Funding sources

1. **Sponsor**
   - **Name of organization / entity**
     - Kermanshah University of Medical Sciences
   - **Full name of responsible person**
     - Dr. Berooz Hamzeh
   - **Street address**
     - Building No. 2, Shahid Beheshti Boulevard, Kermanshah
   - **City**
     - Kermanshah

   **Grant name**
   - Kermanshah University of Medical Sciences

   **Grant code / Reference number**
   - empty

   **Is the source of funding the same sponsor organization/entity?**
   - Yes

   **Title of funding source**
   - Kermanshah 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

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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