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 nonalcoholic 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 daily 500mg 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:
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

Country
Iran (Islamic Republic of)

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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 colori 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 Tests; 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; not consumption of more than 10% of the supplements in any follow-up period

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

Blinding description
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
enzymathic method

2

Description
liver enzymes

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

**Description**
inflammatory markers

**Timepoint**
at first and the end of study

**Method of measurement**
ELISA method

**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 g Accuracy

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 bigest 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**
   Grant code / Reference number
   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: empty
Type of organization providing the funding: empty

Person responsible for general inquiries
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Full name of responsible person
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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