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: 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
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

The effect of quercetin supplementation on nonalcoholic fatty liver disease

Supportive

Inclusion/Exclusion criteria

Inclusion criteria include: a willingness to participation; 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; Not wanting to continue working; 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.

Exclusion criteria included: Not wanting to continue working; diseases that require special treatment; 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

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Secondary Ids

empty

Ethics committees

1

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

3
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
بدو كفواش با استفاده از قد سنگی 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
Ejlaliye Building ,municipal Street, Kermanshah
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Berooz Hamzeh
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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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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