Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of quercetin supplementation on liver enzymes, inflammation indices, lipid profile and body composition, acompaind 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 diease. 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 On 110 men and women with 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 impedence 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-reacrive 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, acompaind 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 participation; 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; 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

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
enzymathic 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 firt of the study and the end of forth,eighth and Twelfth weeks
Method of measurement
BIA

2

Description
weight
Timepoint
at firt 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 firt 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 firt 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 monthsوBe 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 ,municipalStreet, 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
Street address
Building No. 2, Shahid Beheshti Boulevard, Kermanshah
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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
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