

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of quercetin supplementation on liver enzymes, inflammation indices, lipid profile and body composition, accompanied by color 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 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)

Phone

+98 83 3424 3452

Email address

m.hoseinikia@kums.ac.ir

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 color 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 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 weight loss 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

enzymatic 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 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

Ejlaliye Building ,municipalStreet, 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**Type of organization providing the funding**

empty

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Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Mahboobe Hosseinikia

Position

MSc Student in nutritional Sciences

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Faculty of Health, ISAR Field next to Farabi Hospital, Kermanshah University of Medical Sciences

Full name of responsible person

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Position

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Other areas of specialty/work**Street address**

Faculty of Health, ISAR Field next to Farabi Hospital

City**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