

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Investigation of effectiveness of Rosa canina on liver enzymes in patients with nonalcoholic fatty liver

Protocol summary

Summary

This study will be done with aim to investigate the effectiveness of Rosa canina on liver enzymes in patients with nonalcoholic fatty liver. This study is a double blind clinical trial. The study population will be included all patients with fatty liver refer to Red Crescent Clinic of Kermanshah University of Medical Sciences. A total of 70 eligible patients will be selected and will be assigned into two experimental and control groups via block randomization method. In the first stage before the intervention (pre-test), blood sample will be taken from the brachial vein of all people once, after 12 to 14 hours of fasting and about 24 hours before the first practice session. In the intervention group dog rose fractions (fraction of Rosa canina, gelatin solution5% and avicel) will be administered for 8 weeks and the control group will receive placebo (lactose powder, gelatin solution5%, and avicel) for 8 weeks. About 48 hours after the last date of treatment and 12 to 14 hours of fasting, blood samples will be taken again and the liver enzymes will be compared in both groups Inclusion criteria: Diagnosis of non-alcoholic fatty liver disease based on AST and ALT level more than 30 in men and more than 20 in women and also liver ultrasound; Aged between 30-65 years; BMI greater than 25. Exclusion criteria: Using drugs that affect the liver; The risk of diseases that require special treatment; pregnancy during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011514333N65**
Registration date: **2017-03-09, 1395/12/19**
Registration timing: **na**

Last update:

Update count: **0**

Registration date

2017-03-09, 1395/12/19

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Not enough for processing

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-02-08, 1395/11/20

Expected recruitment end date

2016-05-09, 1395/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of effectiveness of Rosa canina on liver enzymes in patients with nonalcoholic fatty liver

Public title

Effect of Rosa canina on non alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of non-alcoholic fatty

diseases based on AST and ALT level more than 30 in men and 20 in women and also liver ultrasound; Aged between 30-65 years; BMI greater than 25; Non-use of antioxidant supplements during one month prior to sampling; Non-acute cardiac disease, renal, infectious, diabetes, hepatitis B or C and other liver diseases; Not being on an intense increasing or decreasing diet weight during the last three months prior to sampling; lack of effective drugs on weight during the last three months prior to sampling; not using medications that may be associated with the disease (methotrexate, amiodarone, tamoxifen, corticosteroids, valproic acid). Exclusion criteria: Not wanting to continue the study; Use of drugs that affect the liver; The risk of diseases that require special treatment; pregnancy during the study.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Crossover

Other design features

Randomization will be done via block randomization.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

City

Kermanshah

Postal code**Approval date**

2017-01-11, 1395/10/22

Ethics committee reference number

kums.rec.1395.593

Health conditions studied**1****Description of health condition studied**

Non alcoholic fatty liver(NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

liver enzymes

Timepoint

Baseline, 48 hours after the end of the study (study will take 8 weeks)

Method of measurement

Based on the results of blood tests (including ALT and AST)

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group will receive a 500 mg pill containing dog rose fractions (fraction of Rosa canina, gelatin solution5% and avicel) per day for 8 weeks.

Category

Treatment - Drugs

2**Description**

The control group will receive a 500 mg placebo pill containing lactose powder, gelatin solution5%, and avicel, per day for 8 weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Red Crescent clinics Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Rozita Nasseri

Street address

Azadi Square

City

Kermanshh

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, 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

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Farzaei

Position

Pharmacist

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

Faculty of Pharmacy, Parastar Boulevard

City

Kermanshah

Postal code**Phone**

+98 83 3426 6780

Fax**Email**

Mh.farzaei@gmail.com

Web page address

Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Rozita Nasseri

Position

Endocrinologist

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

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Postal code**Phone**

+98 834276301

Fax**Email**

rnasseri.75@gmail.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Farzaei

Position

Pharmacist

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

Faculty of Pharmacy, Parastar Boulevard

City

Kermanshah

Postal code**Phone**

+98 834266780

Fax**Email**

Mh.farzaei@gmail.com

Web page address

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