Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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
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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

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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