

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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

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###### 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

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## Person responsible for scientific

## inquiries

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## Person responsible for updating data

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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*