

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of rosehip supplement consumption on fatty liver grade and liver enzymes in comparison with control group in patients with fatty liver

Protocol summary

Summary

The prevalence of fatty liver is estimated about 5.21 - 5.31% in Iran. High prevalence and chronic nature of this disease affects the quality of life of the people and imposes a serious economic burden on society, the effectiveness and safety of pharmacological treatment of NAFLD remains unknown so far. The aim of this study is that the rosehip regarding to its opposite effect to insulin resistance and lipid-lowering serum can control fatty liver. In this double-blind clinical trial, people with fatty liver who referred to this clinic will be invited to participate in the study. Patients were then randomly (random allocation) will be divided into two groups taking supplement and taking placebo. Each patient will receive two can of rosehip capsule or placebo for consume during four weeks. Each supplement capsule contains one gram rosehip and each placebo contains the same amount of corn flour. Duration of supplement intake in this study based on similar studies is considered 16 weeks

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410265968N5**

Registration date: **2017-10-15, 1396/07/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-15, 1396/07/23

Registrant information

Name

Hadis Sabour

Name of organization / entity

Brain and Spinal Injury Research Center (BASIR)

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1560

Email address

hsabour@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Brain and Spinal Injury Research Center (BASIR), Tehran
University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of rosehip supplement consumption on fatty liver grade and liver enzymes in comparison with control group in patients with fatty liver

Public title

The effect of rosehip supplement consumption on fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.Age between 18 and 70 years 2.Fatty liver disease. Exclusion criteria: 1. Alcohol consumption 2.Smoking 3.taking certain medication, such as blood

pressure medications, Insulin sensitivity enhancers, statins, hepatotoxic drugs such as Phenytoin, tamoxifen, lithium and supplements 4. Acute liver disorders such as Hepatitis B and C, liver transplantation, biliary disease known as autoimmune disease, cancer, inherited disorders affecting liver condition (iron and copper storage disease) and other disease 5. Failure to sign the ethical consent.

Age

From **17 years** old to **69 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Other

Other design features

This is a double-blind study; so that not only control and target groups but also the researchers are not aware of the medications. To do this we use a randomization table given by a statistics consult.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tehran University of Medical Sciences.

Street address

Ghods st., Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2015-12-28, 1394/10/07

Ethics committee reference number

IR.TUMS.REC.1394.1503

Health conditions studied

1

Description of health condition studied

fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified
Nonalcoholic fatty liver disease [NAFLD]

Primary outcomes

1

Description

Fatty Liver grade

Timepoint

At the baseline and then after 4 months

Method of measurement

sonography

2

Description

Liver enzymes, SGOT and SGPT

Timepoint

At the baseline and then after 4 months

Method of measurement

blood test

Secondary outcomes

1

Description

Lipid Profile

Timepoint

At the baseline and then after 4 months

Method of measurement

blood test

Intervention groups

1

Description

Intervention group will receive two cans of rosehip supplement for four weeks consume. The amount of consumption of supplement will be 5 gram daily. Each supplement contains 1 gram of rosehip flour. Patients will be advised to take two capsules with breakfast, two with lunch, and one with dinner.

Category

Treatment - Drugs

2

Description

Control group will receive two cans of placebo for four weeks consume. The amount of consumption of placebo will be 5 gram daily. Each placebo contains 1 gram of corn flour. Patients will be advised to take two capsules with breakfast, two with lunch, and one with dinner

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and Spinal Injury Research Center (BASIR)

Full name of responsible person

Hadis Sabour

Street address

Reihane building, Imam Khomeini Hospital, Gharib St.,
Keshavarz Blvd.,Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Brain and Spinal injury Research Centre

Full name of responsible person

Dr. Abbas Norouzi Javidan

Street address

Reihane building, Imam Khomeini Hospital, Gharib St.,
Keshavarz Blvd.,Tehran, Iran

City

Tehran

Grant name

طرح رزهیپ

Grant code / Reference number

93-03-85-26941

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Brain and Spinal injury Research Centre

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**

Brain and Spinal Injury Research Centre

Full name of responsible person

samira tabrizian

Position

MSC of nursing

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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Nutrition Expert

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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