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

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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

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Position
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Other areas of specialty/work

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Person responsible for updating data

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Position
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Other areas of specialty/work

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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