

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of supplementation with sumac powder on liver enzymes (Alanine aminotransferase and Aspartate aminotransferase), lipid profiles (Triglyceride, Total cholesterol, High density lipoprotein, Low density lipoprotein), leptin and liver steatosis in patients with non-alcoholic fatty liver disease: a randomized controlled clinical trial

Protocol summary

Summary

Objective: The effect of supplementation with sumac on liver enzymes (Alanine aminotransferase and Aspartate aminotransferase), lipid profiles (Triglyceride, Total cholesterol, High density lipoprotein, Low density lipoprotein), leptin, steatosis of the liver in patients with nonalcoholic fatty liver (Clinical Trial randomized controlled group) study population of patients (men and women) 20-60 years old, with non-alcoholic fatty liver referring to research and treatment Sedighe Tahereh . with Preliminary analysis, criteria for cooperation. A sample of 80 people. During this 12-week study. 40 patients in the group receiving sumac (daily dose of 2g sumac as 4 capsules of 500 mg) and 40 in the placebo group (daily dose of 2g dextrin as 4 capsules of 500 mg). at the beginning and end of the study, factors such as anthropometric measurements, blood pressure, Alanine aminotransferase and Aspartate aminotransferase , lipid profile (Triglyceride, Total cholesterol, High density lipoprotein, Low density lipoprotein), leptin and liver steatosis, a 24-hour recall for 3 days (for 2 days mid-week and 1 weekend day) and international physical activity questionnaire will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701162709N39**

Registration date: **2017-05-06, 1396/02/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-06, 1396/02/16

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

iran University Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplementation with sumac powder on liver enzymes (Alanine aminotransferase and Aspartate aminotransferase), lipid profiles (Triglyceride, Total cholesterol, High density lipoprotein, Low density lipoprotein), leptin and liver steatosis in patients with

non-alcoholic fatty liver disease: a randomized controlled clinical trial

Public title

The effect of sumacl on fatty liver disease

Purpose

Supportive

Inclusion/Exclusion criteria

The criteria for inclusion: Age 20-60 years of both sexes, fatty liver disease be approved by physician gastroenterologist based on the following criteria: (ultrasound, volume Elastometry in fiberscan and > 4 kPa (kpa) or are in the process of steatosis S1 and Alanine transferase more than 5.1 times the upper limit of normal (women and men), Body Mass Index (BMI)25-29/9), a interested in participating the plan and received written informed consent, lack of participation in other projects. Exclusion criteria:The patient's unwillingness to continue cooperation with the Started taking the drug during the intervening period, Change the type or dose, Change in diet or physical activity program, Weight loss more than 10% of initial body weight during the intervention , Any use of antioxidant supplements, vitamins or minerals , Less than 80% supplements delivered to the patient at baseline, Start smoking during the intervening period, Become pregnant during treatment, Surgery and psychosomatic problems during the intervention, The use of all anti-NASH (vitamin E, thiazolidinedione, UDCA gemfibrozil,), Developing other liver diseases, kidney, kidney stones, cancer, hypothyroidism or hyperthyroidism, allergies, trauma during the intervention

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

The ethics committee the University of Medical Sciences Iran

Street address

School of Public Health,Iran University Medical Sciences,The intersection of Sheikh Fazlollah and shahid Chamran,Hemmat Highway,Tehran

City

Tehran

Postal code**Approval date**

2016-11-08, 1395/08/18

Ethics committee reference number

IR.IUMS.REC 1395.95-03-27-29491

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

Nonalcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

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

Alanine aminotransferase

Timepoint

Before the start of treatment and 12 weeks after intervention

Method of measurement

Spectrophotometry

2**Description**

Aspartate aminotransferase

Timepoint

Before the start of treatment and 12 weeks after intervention

Method of measurement

Spectrophotometry

3**Description**

Hepatic steatosis

Timepoint

Before the start of treatment and 12 weeks after intervention

Method of measurement

Using the scanning fiber 502

Secondary outcomes

1

Description

Total cholesterol

Timepoint

Before the start of treatment and 12 weeks after intervention

Method of measurement

Spectrophotometry

2

Description

Triglycerides

Timepoint

Before the start of treatment and 12 weeks after intervention

Method of measurement

Spectrophotometry

3

Description

Low density lipoprotein

Timepoint

Before the start of treatment and 12 weeks after intervention

Method of measurement

Spectrophotometry

4

Description

High density lipoprotein

Timepoint

Before the start of treatment and 12 weeks after intervention

Method of measurement

Spectrophotometry

5

Description

Leptin

Timepoint

Before the start of treatment and 12 weeks after intervention

Method of measurement

Elisa

Intervention groups

1

Description

Control group: daily 2 g dextrin as 4 capsules of 500 mg

Category

Treatment - Drugs

2

Description

Intervention group: daily 2 g sumac as 4 capsules of 500 mg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sedigheh Tahereh of Research and Clinical Center

Full name of responsible person

Simin Ehsani

Street address

Sedigheh Tahereh of Research and Clinical Center, Khorram of streets, Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Iran university Medical Sciences

Full name of responsible person

Doctor Syed Ali Javad Mousavi, deputy head of Research and Technology, Iran University Medical Sciences

Street address

School of Public Health, Iran University Medical Sciences, The intersection of Sheikh Fazlollah and Shahid Chamran, Hemmat Highway, Tehran

City

Tehran

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 of Iran university 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

Iran University Medical Sciences

Full name of responsible person

Dr Farzad Shidfar

Position

Department of Nutrition Sciences, Professor

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

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Fax

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