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 cholestrol,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 cholestrol,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 cholestrol,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

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Iran University of Medical Sciences
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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 cholestrol,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 Alastvmtry 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 Fazllolallah 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 cholestrol
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
Sedighe 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 Scien
Street address
School of Public Health,Iran University Medical Sciences,The intersection of Sheikh Fazllolallah 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

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Web page address

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