Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Investigation the effect of the Sumac powder on Liver Enzymes, lipid profile, glycemic indexes, Antioxidant marker, inflammatory marker, anthropometric measurements in non-alcoholic fatty liver patients with overweight or obes

Protocol summary

Study aim
Investigation the effect of the sumac powder consumption on liver enzymes, lipid profile, glycemic index, inflammatory index and antioxidant index and anthropometric measurements in overweight or obese non-alcoholic fatty liver patients.

Design
randomized, double-blind, clinical trial with intervention and control groups

Settings and conduct
Patients referring to liver clinic of Motahari clinic, If they meet the inclusion criteria, they will be randomly assigned into two groups. Blindness will be such that supplements and placebo supplements will receive A and B labels and the supplement provider and the patient will not be aware of their condition.

Participants/Inclusion and exclusion criteria
Desire to participate in study Male or female 20-60 years old Patient who diagnosed NAFLD with using ultrasound by physician The power of decision making and the ability to do life without the help of others BMI = 25- 35 No history of alcohol using No history of liver cirrhosis Lack of other chronic and acute liver disorders (hepatitis B, C, etc.) and effective hereditary diseases, cancers and hereditary infections affecting the liver (iron storage disease, copper, etc.) Lack of using of blood lipids, blood sugar, vitamin E and UDCA and hepatotoxic drugs such as phenytoin, amoxifen and lithium. Lack of celiac disease, diabetes, cardiovascular disease, pulmonary and kidney disease, no history of thyroid problems No history of weight loss surgery, no recent weight loss plan in 3 months Lack of supplementation of fiber, omega-3 and antioxidants in 3 months ago

Intervention groups
Intervention group: Supplement of Sumac powder (3gr/day)+ diet Control group: Starch supplement(3gr/day) (placebo) +diet

Main outcome variables
Weight,Height,Waist,Hip circumference,Waist to hip ratio,Body Mass Index,Fat Mass, FreeFat Mass, TBW,BCM, Chol,TG, LDL,HDL, FBS ,Insulin,TAC,TNFa, AST/GGT/ALT,ALKP

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191009045043N1**
Registration date: **2020-01-20, 1398/10/30**
Registration timing: **prospective**

Last update: **2020-01-20, 1398/10/30**
Update count: **0**

Registration date
2020-01-20, 1398/10/30

Registrant information

Name
Mohsen Mohit
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 3726 7056
Email address
mohsen.mohit20@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of the Sumac powder on Liver Enzymes, lipid profile, glycemic indexes, Antioxidant marker, inflammatory marker, anthropometric measurements in non-alcoholic fatty liver patients with overweight or obes

Public title

Investigation The effect of the Sumac powder consumption on patients with non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Desire to participate in study Male or female 20-60 years old Patient who diagnosed NAFLD with using ultrasound by physician The power of decision making and the ability to do life without the help of others BMI : 25- 35

Exclusion criteria:

No history of alcohol using No history of liver cirrhosis Lack of other chronic and acute liver disorders (hepatitis B, C, etc.) and effective hereditary diseases, cancers and hereditary infections affecting the liver (iron storage disease, copper, etc.) Lack of using of blood lipids, blood sugar, vitamin E and UDCA and hepatotoxic drugs such as phenytoin, amoxifen and lithium Lack of celiac disease, diabetes, cardiovascular disease, pulmonary and kidney disease, no history of thyroid problems No history of weight loss surgery, no recent weight loss plan in 3 months Lack of supplementation of fiber, omega-3 and antioxidants in 3 months ago

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on block randomization and 4 blocks, the entry of patients into the two study groups will be randomized by using the website www.randomization.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding method will be that the complement packages of sumac and placebo will receive the labels A and B, only the assistant professor will know the status of placebo and supplements and the supplement provider and the patient will not know about it.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz, zand Ave, Shiraz University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

14336- 71348

Approval date

2019-10-09, 1398/07/17

Ethics committee reference number

IR.SUMS.REC.1398.914

Health conditions studied

1

Description of health condition studied

Nonalcoholic Fatty Liver Disease

ICD-10 code

K77

ICD-10 code description

Liver disorders in diseases classified elsewhere

Primary outcomes

1

Description

Alanine aminotransferase (ALT) enzyme

Timepoint

Baseline and the end of the intervention

Method of measurement

ALT kit

2

Description

Aspartate aminotransferase (AST) enzyme
Timepoint
Baseline and the end of the intervention
Method of measurement
AST kit

3

Description
Weight
Timepoint
Baseline and the end of the intervention
Method of measurement
scale/ kg

4

Description
Cholestrol
Timepoint
Baseline and the end of the intervention
Method of measurement
Cholestrol Kit

5

Description
Triglyceride
Timepoint
Baseline and the end of the intervention
Method of measurement
Triglyceride Kit

6

Description
Low-density lipoprotein
Timepoint
Baseline and the end of the intervention
Method of measurement
Low-density lipoprotein Kit

7

Description
High-density lipoprotein
Timepoint
Baseline and the end of the intervention
Method of measurement
High-density lipoprotein Kit

8

Description
Fasting blood suger
Timepoint
Baseline and the end of the intervention
Method of measurement
Fasting blood suger Kit

9

Description
Insulin
Timepoint
Baseline and the end of the intervention
Method of measurement
Insulin Kit

10

Description
Total Antioxidant Capacity
Timepoint
Baseline and the end of the intervention
Method of measurement
Total Antioxidant Capacity Kit

11

Description
Tumor Necrosis Factor alpha
Timepoint
Baseline and the end of the intervention
Method of measurement
Tumor Necrosis Factor alpha Kit

12

Description
Alkaline Phosphatase
Timepoint
Baseline and the end of the intervention
Method of measurement
Alkaline Phosphatase kit

13

Description
Height
Timepoint
Baseline and the end of the intervention
Method of measurement
Meter

14

Description
Waist circumference
Timepoint
Baseline and the end of the intervention
Method of measurement
Meter

15

Description
Hip circumference
Timepoint
Baseline and the end of the intervention
Method of measurement
Meter

16

Description
Fat mass
Timepoint

Baseline and the end of the intervention
Method of measurement
BIA device

17

Description
Fat Free mass
Timepoint
Baseline and the end of the intervention
Method of measurement
BIA device

18

Description
Total Body Water
Timepoint
Baseline and the end of the intervention
Method of measurement
BIA device

19

Description
Body cell mass
Timepoint
Baseline and the end of the intervention
Method of measurement
BIA device

20

Description
gama glutamil transferase enzyme
Timepoint
Baseline and the end of the intervention
Method of measurement
gama glutamil transferase KIt

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Sumac powder capsule + diet
Category
Treatment - Drugs

2

Description
Control group: Medicinal starch capsule + diet
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Clinic and Other Liver and Gastroenterology Clinics of Shiraz University of
Full name of responsible person
Najmeh hejazi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohsen Mohit

Position
MS.c of Clinical Nutrition

Latest degree
Master

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

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Najmeh Hejazi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Mohsen Mohit

Position
MS.c of Clinical Nutrition

Latest degree
Master

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available