

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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/SGT/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)

##### Phone

+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](http://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**  
Cholesterol  
**Timepoint**  
Baseline and the end of the intervention  
**Method of measurement**  
Cholesterol 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 sugar  
**Timepoint**  
Baseline and the end of the intervention  
**Method of measurement**  
Fasting blood sugar 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

**Street address**

Namazi Square, Motahari Clinic

**City**

Shiraz

**Province**

Fars

**Postal code**

71348-14336

**Phone**

+98 71 3230 5410

**Email**

nhejazi@sums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Younes Qasemi

**Street address**

Zand Ave, Shiraz University of Medical Science

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**Province**

Fars

**Postal code**

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**Phone**

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**Email**

vcrdep@sums.ac.ir

**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

**Street address**

Razi Blvd, Nutrition School of Shiraz University of  
Medical Sciences

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**Province**

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**Postal code**

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**Phone**

+98 71 3725 1001

**Email**

mohsen.mohit20@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Najmeh Hejazi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

### 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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**Postal code**

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**Email**

mohsen.mohit20@yahoo.com

## 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