

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Sep 2026

Comparison of the effects of Sumac supplementation plus calorie-restricted diet versus calorie-restricted diet alone on inflammatory markers, oxidative stress, and fasting blood glucose in patients with Non-Alcoholic Fatty Liver Disease (NAFLD)

Protocol summary

Study aim

This study is designed to investigate the effects of sumac on inflammatory status, oxidative stress, and glycemic indices in individuals with non-alcoholic fatty liver disease (NAFLD).

Design

A phase 3, double-blind, randomized, parallel-group controlled clinical trial on 62 patients. Stratified blocks will be used for randomization.

Settings and conduct

Study location: Nutrition Clinic, Allameh Behloul Gonabadi Hospital, Gonabad. Study population: 62 patients receiving medical treatment. Type of blinding: Double-blind. Blinding procedure: Pills will be pre-coded as A and B by someone other than the researcher to keep both the researcher and patients unaware of their contents.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Presence of hepatic fat accumulation on liver ultrasound and grade 2 fatty liver disease; elevated liver enzymes (ALT and AST > 40 U/L); age between 20 and 60 years; body mass index (BMI) greater than 25 kg/m²; ability to read and write. Exclusion criteria: History of chronic diseases such as diabetes, cardiovascular, or kidney disorders; use of dietary supplements or herbal medicines within the past three months; pregnancy; lactation; use of medications that affect liver function; known allergy to sumac or related products.

Intervention groups

Intervention group: Participants will receive standard medical treatment under internist supervision and will take 1500 mg of sumac supplement daily, divided into three 500 mg doses, for 12 weeks. Control group: Participants will receive standard medical treatment under internist supervision and will take 1500 mg of

placebo (corn starch) daily, divided into three 500 mg doses, for 12 weeks.

Main outcome variables

Total antioxidant capacity; alanine aminotransferase; aspartate aminotransferase; malondialdehyde; C-reactive protein; tumor necrosis factor-alpha; interleukin-10

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250527065918N1**

Registration date: **2025-08-31, 1404/06/09**

Registration timing: **prospective**

Last update: **2025-08-31, 1404/06/09**

Update count: **0**

Registration date

2025-08-31, 1404/06/09

Registrant information

Name

Elyas Nattagh Eshtivani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3028

Email address

nattagh.e@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-21, 1404/06/30

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Sumac supplementation plus calorie-restricted diet versus calorie-restricted diet alone on inflammatory markers, oxidative stress, and fasting blood glucose in patients with Non-Alcoholic Fatty Liver Disease (NAFLD)

Public title

The Effect of Sumac and a Low-Calorie Diet on Improving Fatty Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Individuals aged 20 to 60 years Presence of fat accumulation in liver ultrasound evaluation with Grade 2 fatty liver and elevated liver enzymes (ALT and AST > 40) Ability to read and write Body Mass Index (BMI) greater than 25 kg/m²

Exclusion criteria:

Having chronic lung diseases, other liver diseases, heart conditions, and any chronic kidney or digestive disease History of drinking alcoholic beverages Smoking and drug abuse Use of diuretics and nonsteroidal anti-inflammatory drugs (NSAIDs), estrogen, tamoxifen, corticosteroids, and blood sugar-lowering drugs within 3 weeks before the start of the study and during the study Evidence of viral hepatitis infection Pregnancy Breast feeding Follow of special diet Regular consumption of antioxidant supplements such as vitamins E, C, and silymarin

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

To allocate participants into the intervention group (receiving sumac supplement) and the control group (receiving placebo), stratified block randomization will be used. Stratification will be based on body mass index

(BMI: <30 or ≥30 kg/m²) and gender (male or female) to ensure balanced distribution within each stratum. A list of eligible participants will be prepared, and each individual will be categorized into one of four strata: female with BMI<30, female with BMI≥30, male with BMI<30, and male with BMI≥30. Then, within each stratum, participants will be randomly assigned to either group using Randomization.com (available at: <https://www.randomization.com>) with a block size of 4. The randomization list will only be accessible to the researcher responsible for allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

To ensure proper blinding, the supplement and placebo will be identical in color, size, and odor, and neither the participants nor the researchers except for the pharmacist will be aware of their contents until the end of the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committee of Gonabad University of Medical Sciences

Street address

Mehdizadeh boulevard

City

Gonabad

Province

Razavi Khorasan

Postal code

9691699967

Approval date

2025-01-18, 1403/10/29

Ethics committee reference number

IR.GMU.REC.1403.114

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

Non alcoholic fatty liver

ICD-10 code

K75

ICD-10 code description

Other inflammatory liver diseases

Primary outcomes

1

Description

Oxidative stress status (MDA)

Timepoint

Initially and 12 weeks (84 days) after starting sumac supplementation

Method of measurement

ELISA Kit

2

Description

Blood glucose

Timepoint

Initially and 12 weeks (84 days) after starting sumac supplementation

Method of measurement

Biochemical kit

3

Description

C reactive protein

Timepoint

Initially and 12 weeks (84 days) after starting sumac supplementation

Method of measurement

ELISA Kit

4

Description

Tumor Necrosis Factor alpha (TNF- α)

Timepoint

Initially and 12 weeks (84 days) after starting sumac supplementation

Method of measurement

ELISA Kit

5

Description

Interleukin 10 (IL-10)

Timepoint

Initially and 12 weeks (84 days) after starting sumac supplementation

Method of measurement

ELISA Kit

6

Description

Total antioxidant capacity (TAC)

Timepoint

Initially and 12 weeks (84 days) after starting sumac supplementation

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

Alanine aminotransferase

Timepoint

Initially and 12 weeks (84 days) after starting sumac supplementation

Method of measurement

Biochemical kit

2

Description

Aspartate aminotransferase

Timepoint

Initially and 12 weeks (84 days) after starting sumac supplementation

Method of measurement

Biochemical kit

Intervention groups

1

Description

Intervention group: 1500 mg of Sumac powder supplement daily in three divided doses of 500 mg for 12 weeks

Category

Treatment - Other

2

Description

Control group: 500 mg daily of placebo (corn starch) with a color and odor similar to sumac, daily in three divided doses of 500 mg for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Allameh Bohlul Specialized Clinic, Gonabadi Hospital

Full name of responsible person

Elyas Nattagh Eshtivani

Street address

Mahdizadeh boulevard

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Phone

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Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

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

Gonabad 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**

Gonabad University of Medical Sciences

Full name of responsible person

Elyas Nattagh Eshtivani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After completion of the study and publication of the results, the raw data will be made available to interested

researchers upon request. Access will be provided through direct contact with the corresponding author and subject to approval by the ethics committee.

When the data will become available and for how long

After the project is completed (6 months after the results are published)

To whom data/document is available

Only for researchers working in academic institutions

Under which criteria data/document could be used

People working in research centers.

From where data/document is obtainable

Sending request to email: nattagh.elyas@gmail.com

What processes are involved for a request to access data/document

A maximum of 30 working days

Comments