Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Aug 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 Behlool 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

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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
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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
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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