Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the Efficacy and Safety of a Syrup Containing Processed Chicory (Cichorium intybus) Extract and Vitamin E on Disease Severity in Patients with Non Alcoholic Fatty Liver Disease: A Randomized, Double Blind, Placebo Controlled Clinical Trial

Protocol summary

Study aim

Evaluation of the effects of a syrup containing processed chicory extract and vitamin E on liver parameters, lipid profile, hepatic fat content, and liver stiffness in patients with Grade 2 Non Alcoholic Fatty Liver Disease

Design

This randomized, double blind, placebo controlled, parallel group trial will include 106 patients withGrade 2 Non Alcoholic Fatty Liver Disease, equally assigned to intervention and placebo groups (53 each) using block randomization generated by the RAND function in Microsoft Excel

Settings and conduct

The principal investigator will prepare the randomization list, recruit and allocate participants, and dispense herbal products according to randomization codes. Data collection will be performed by the investigator, while laboratory tests and assessments will be conducted by a laboratory expert at Valiasr Hospital, Arak University of Medical Sciences, Iran

Participants/Inclusion and exclusion criteria

A total of 106 patients aged 20 to 60 years with Grade 2 Non Alcoholic Fatty Liver Disease confirmedby laboratory tests, ultrasonography, and FibroScan will be enrolled. Participants must provide informed consent and have no history of alcohol use, pregnancy, other herbal medicine use, or chicory allergy. Those who withdraw consent or develop adverse events will be excluded

Intervention groups

Participants in this randomized, double blind, placebo controlled trial will be allocated to intervention or placebo groups. The intervention group will receive three tablespoons daily of hydro alcoholic chicory extract and vitamin E syrup for three months, while the placebo group will receive an identical preparation in appearance, taste, and volume.

Main outcome variables

Baseline assessments will include lipid profile, platelet count, liver enzymes, waist circumference blood pressure, body mass index, liver stiffness, and hepatic fat content measured by Fibro Scan.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260623069924N1**
Registration date: **2026-07-11, 1405/04/20**
Registration timing: **prospective**

Last update: **2026-07-11, 1405/04/20**
Update count: **0**

Registration date

2026-07-11, 1405/04/20

Registrant information

Name

Nafiseh Noormohammadi feyjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-06, 1405/06/15

Expected recruitment end date
2026-12-06, 1405/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Efficacy and Safety of a Syrup Containing Processed Chicory (Cichorium intybus) Extract and Vitamin E on Disease Severity in Patients with Non Alcoholic Fatty Liver Disease: A Randomized, Double Blind, Placebo Controlled Clinical Trial

Public title
"Effects of a Syrup Containing Chicory Extract and Vitamin E in Patients with Non Alcoholic Fatty Liver Disease"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Total cholesterol level greater than or equal to 240 mg/dL. Triglyceride level greater than or equal to 500 mg/dL Low density lipoprotein cholesterol level greater than or equal to 130 mg/dL High density lipoprotein cholesterol level greater than or equal to 40 mg/dL. Alanine aminotransferase level greater than or equal to 35 U/L Aspartate aminotransferase level greater than or equal to 35 U/L Fibro Scan findings demonstrating liver stiffness within the moderate fibrosis range (7 to 9.5 kPa) and Controlled Attenuation Parameter (CAP) greater than 290 dB/m.. Age between 20 and 60 Years Non pregnant women Willingness to participate in the study and provision of written informed consent Known No allergy to chicory or its components No concurrent use of other herbal medicines besides the prescribed study treatment No alcohol consumption
Exclusion criteria:
Participant's decision to receive alternative treatments during the study period Occurrence of allergic reactions or treatment related adverse events
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
To ensure balanced distribution of variables such as age, sex, disease severity, and lifestyle factors between the intervention and placebo groups, block randomization will be used. Randomization will be performed using blocks of four participants with six possible allocation sequences (AABB, ABAB, BAAB, ABBA, BABA, and BBAA), where A represents the intervention group and B represents the placebo group. The random allocation sequence will be generated using the RAND function in Microsoft Excel. The unit of randomization will be the individual participant.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted as a double blind trial. Participants and the investigator will be unaware of treatment allocation. The intervention product and placebo will be identical in appearance, color, odor, taste, volume, and packaging. Study products will be labeled and coded according to the randomization list by a pharmacist or an independent person not involved in participant assessment. Treatment allocation codes will remain confidential until study completion. Participants will be assigned to study groups based on the randomization code on the package. The investigator, participants, laboratory expert, and outcome assessor will remain blinded to group allocation throughout the study. Unblinding will be permitted only after completion of data collection and analysis or in the event of a medical emergency.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Payambar-e-Azam University Campus, Arak University of Medical Sciences, Basij Square, Sardasht Boulevard, Arak, Iran
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2026-05-10, 1405/02/20
Ethics committee reference number
IR.ARAKMU.REC.1405.092

Health conditions studied

1

Description of health condition studied
Nonalcoholic Fatty Liver Disease (NAFLD)
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Serum Alanine Aminotransferase (ALT) Level
Timepoint
Before and after the 3-month intervention
Method of measurement
Serum alanine aminotransferase level measured using standard laboratory methods

Secondary outcomes

1

Description
Serum alanine aminotransferase level measured using standard laboratory methods
Timepoint
methods before and after the 3-month intervention
Method of measurement
Measured in venous blood samples using an automated biochemical analyzer. U/L

2

Description
Serum aspartate aminotransferase level measured using standard laboratory
Timepoint
methods before and after the 3-month intervention
Method of measurement
Measured in venous blood samples using an automated biochemical analyzer.U/L

3

Description
Serum triglyceride concentration measured by enzymatic laboratory methods at baseline and after intervention
Timepoint
methods before and after the 3-month intervention
Method of measurement
Measured in fasting serum samples using enzymatic colorimetric methods.mg/dL

4

Description
Serum total cholesterol concentration measured using standard biochemical assays
Timepoint
methods before and after the 3-month intervention
Method of measurement
Measured in fasting serum samples using enzymatic colorimetric methods.mg/dL

5

Description
Serum total cholesterol concentration measured using standard biochemical assays
Timepoint
methods before and after the 3-month intervention
Method of measurement
Measured in fasting serum samples using enzymatic colorimetric methods.mg/dL

6

Description
Serum low-density lipoprotein cholesterol level measured
Timepoint
methods before and after the 3-month intervention
Method of measurement
Measured in fasting serum samples using an automated biochemical analyzer.mg/dL

7

Description
Serum high-density lipoprotein cholesterol level measured at baseline
Timepoint
methods before and after the 3-month intervention
Method of measurement
Measured in fasting serum samples using an automated biochemical analyzer.mg/dL

8

Description
Body mass index calculated
Timepoint
methods before and after the 3-month intervention
Method of measurement
weight in kilograms divided by height in meters/kg/m^2

9

Description
adverse events
Timepoint
methods before and after the 3-month intervention
Method of measurement
Number and type of adverse events reported by participants or observed by investigators during the 3-month intervention period with chicory product or placebo

10

Description

Liver Stiffness)

Timepoint

methods before and after the 3-month intervention

Method of measurement

Fibro Scan

11

Description

Peripheral blood platelet

Timepoint

methods before and after the 3-month intervention

Method of measurement

measured using an automated hematology analyzer.×10^3/µL

Intervention groups

1

Description

Intervention group: Participants with Grade 2 Non Alcoholic Fatty Liver Disease will receive a syrup containing 4 g of processed hydro alcoholic powdered extract of chicory (Cichorium intybus) and 13.5 mg of vitamin E per 100 mL of syrup. The prescribed dose is three tablespoons (approximately 15 g) daily for 3 months.

Category

Treatment - Drugs

2

Description

Control group: Participants in the placebo group will receive a placebo syrup packaged in containers identical to those used for the intervention product. The placebo consists of an aqueous solution containing a small amount of chicory flavored essence and is identical to the intervention product in terms of appearance, color, odor, taste, volume, and packaging. It will be administered at the same dose and according to the same dosing schedule as the intervention group, that is, three tablespoons daily for 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr hospital

Full name of responsible person

Nafiseh Noormohammadi feyjani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Behzad Khansarinejad

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Vice Chancellor for Research and Technology, Payambar-e-Azam University Campus, Arak University of Medical Sciences, Basij Square, Sardasht Boulevard, Arak, Iran

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Grant name

0

Grant code / Reference number

0

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Nafiseh Noormohammadi feyjani
Position
Researcher
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
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Person responsible for scientific inquiries

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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
Yes - There is 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
De-identified individual participant data including demographic characteristics (age, sex), anthropometric measurements (BMI, waist circumference), blood pressure, laboratory parameters (ALT, AST, triglycerides, total cholesterol, LDL-C, HDL-C, platelet count), and FibroScan results (CAP score and liver stiffness measurement) collected at baseline and after 3 months of intervention.
When the data will become available and for how long
The data will be available from the time of publication of the primary study results and will remain accessible for 5 years after publication.
To whom data/document is available
Applicants must submit a formal request to the Principal Investigator of the study. Following review and approval of the request by the research team, and in compliance with participant confidentiality and data protection requirements, the requested data will be made available

through encrypted electronic files.

Under which criteria data/document could be used

The study data will be available for scientific research, educational purposes, and secondary analyses. Applicants must submit a formal request to the principal investigator. Access will be granted after review and approval by the research team and subject to protection of participant confidentiality through de identification of data. Data may be used only for the approved scientific purposes and in accordance with research ethics requirements.

From where data/document is obtainable

Applicants must submit a formal request to the Principal Investigator of the study. Following review and approval of the request by the research team, and in compliance with participant confidentiality and data protection requirements, the requested data will be made available through encrypted electronic files.

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

Applicants must submit a formal request to the Principal Investigator of the study. Following review and approval of the request by the research team, and in compliance with participant confidentiality and data protection requirements, the requested data will be made available through encrypted electronic files.

Comments