Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the Effects of a Low Acid Load Diet and N-Acetylcysteine Supplementation on Hepatic Steatosis, Biochemical, Anthropometric, and Blood Pressure Indices in Patients with Non-Alcoholic Fatty Liver Disease

Protocol summary

Study aim

Determining the effect of low acid load diet and N-Acetylcysteine (NAC) supplementation on hepatic steatosis, biochemical, anthropometric and blood pressure indices in patients with non-alcoholic fatty liver disease (NAFLD)

Design

Clinical trial with control group, parallel groups, single blind, on 66 patients, randomization based on the steatosis severity will be done using the website.

Settings and conduct

Eligible participants for the study will be recruited from individuals visiting the Liver and Gastrointestinal Clinic at Motahari Clinic. They will be randomly assigned to one of three groups. Participants will be referred to Imam Reza Clinic for anthropometric evaluations and will receive a diet along with supplement or a placebo. The participants will be blinded to their group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Literate NAFLD patients aged 18-60, with a Controlled Attenuation Parameter (CAP) score ≥260 dB/m and Liver Stiffness Measurement (LSM) ≤9.4 kPa , 25 ≤ body mass index ≤ 35; receiving consistent treatment in participants suffering dyslipidemia or hypertension. Exclusion Criteria: Pregnancy, breastfeeding, other liver diseases, diabetes, kidney issues, or mental health disorders; alcohol consumption above 20 g/d (women) or 30 g/d (men); recent use of hormonal or weight-affecting medications; prior bariatric surgery; antioxidant supplementation ;hospitalization and infection in the past two weeks.

Intervention groups

Participants in this study will be divided into two intervention groups and one control group. Group 1: 600 mg NAC (two tablets daily) + healthy diet. Group 2: Low acid load diet + two starch tablets daily. Group 3: Healthy diet + two starch tablets daily.

Main outcome variables

CAP score; LSM; Liver enzymes; Serum glutathione; Fasting blood sugar and insulin; Insulin resistance; Lipid profile; Anthropometric indices; Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240901062927N1**
Registration date: **2024-09-09, 1403/06/19**
Registration timing: **prospective**

Last update: **2024-09-09, 1403/06/19**
Update count: **0**

Registration date

2024-09-09, 1403/06/19

Registrant information

Name

Sara Bashiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

bashiriisara@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-05, 1403/07/14

Expected recruitment end date

2024-11-19, 1403/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Effects of a Low Acid Load Diet and N-Acetylcysteine Supplementation on Hepatic Steatosis, Biochemical, Anthropometric, and Blood Pressure Indices in Patients with Non-Alcoholic Fatty Liver Disease

Public title

Effects of a Low Acid Load Diet and NAC Supplementation on Hepatic Steatosis and Metabolic Factors in NAFLD Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Literate individuals diagnosed with NAFLD, exhibiting moderate to severe steatosis based on gastroenterology and liver specialist evaluations, with a CAP score of ≥260 dB/m obtained from a fibroscan Absence of pregnancy, breastfeeding, other liver diseases, hepatic encephalopathy, malignancies, diabetes mellitus, kidney disorders and mental health issues Fibroscan should have been conducted within the last three weeks Participants must have a body mass index between 25 and 35 (25≤BMI≤35) and a liver stiffness measurement (LSM) of ≤9.4 kPa Individuals who drink little or no alcohol (defined as < 20 g/d for women and < 30 g/d for men) No history of hormonal medication or weight-affecting drugs within the past three months, nor previous bariatric surgery or current antioxidant supplementation Individuals on fixed treatments for dyslipidemia or hypertension, with no history of infection, surgery, trauma, or hospitalization in the last two weeks

Exclusion criteria:

Individuals who become pregnant during the study or fail to return for follow-up assessments Participants demonstrating less than 70% adherence to diet or less than 80% adherence to supplement intake Occurrence of gastrointestinal side effects related to supplement use

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

To ensure the integrity of the study, participants will be divided into three groups: two intervention groups and one control group. This division will be achieved using Stratified permuted block randomization , based on two levels of hepatic steatosis severity (moderate and severe), as determined by the CAP score obtained from FibroScan results. The allocation will utilize a reliable online tool for randomization, accessible at: https://www.sealedenvelope.com/simple-randomiser/v1/lists Once the random allocation sequence is established, the groups will be labeled with conventional names: A, B, and C. These names will be placed in sealed envelopes according to the predetermined sequence, which will be numbered sequentially. After participants enter the study and complete their initial assessments, a sealed envelope corresponding to their order of entry will be opened. This envelope will contain the assigned group's conventional name, which was determined by an external party not involved in the study. This method ensures that the allocation sequence remains concealed from the research team, maintaining the blinding necessary for unbiased implementation.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, two main interventions, one in the form of diet and the other in the form of supplements, are presented to the patients. Since designing and presenting the diet and teaching it to the patient is the responsibility of the principal investigator , and it is not possible to blind the trainer, the present intervention will be performed in a single blind manner. At the outset of the study, the principal investigator will coordinate with participants, oversee the study's implementation, and gather baseline data. Throughout the intervention, the principal investigator will engage in various activities, including making phone calls, monitoring diet and physical activity, sending text messages, and conducting face-to-face meetings with participants. Following the completion of the intervention, the principal investigator will also assess anthropometric indicators. Finally, the principal investigator will be responsible for the final data collection, statistical analysis, and preparation of the final report.

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

Central building of Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2024-08-04, 1403/05/14

Ethics committee reference number

IR.SUMS.SCHEANUT.REC.1403.036

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver disease (NAFLD)

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Levels of liver enzymes (AST , ALT)

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Using a special kit and an autoanalyzer device

2

Description

Serum glutathione

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Using a special kit and an autoanalyzer device

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Using a special kit and an autoanalyzer device

2

Description

Fasting insulin

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Using ELIZA kits and a ELIZA reader device

3

Description

Lipid profile (HDL, LDL, Total cholesterol, Triglycerides)

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Using a special kit and an autoanalyzer device

4

Description

Liver stiffness measurement (LSM)

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Vibration-controlled transient elastography (fibroscan)

5

Description

Insulin resistance indices (HOMA-IR & QUICKI)

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Using special formulas containing fasting blood sugar and insulin

6

Description

Blood pressure

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Using a sphygmomanometer

7

Description

Anthropometric indices

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Using meter, body analyzer device and special formulas

8

Description

Controlled attenuation parameter (CAP) score

Timepoint

At the beginning of the study and 12 weeks after the intervention

Method of measurement

Vibration-controlled transient elastography (fibroscan)

Intervention groups

1

Description
Intervention group 1 : 1200 mg N-acetylcysteine (two tablets) daily + healthy diet.
Category
Treatment - Other

2

Description
Intervention group 2 : Low acid load diet + two starch tablets daily
Category
Treatment - Other

3

Description
Control group: Healthy diet + two starch tablets daily
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari Clinic
Full name of responsible person
Afsane Ahmadi
Street address
Razi Blvd
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7134814336
Phone
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ahmadi.afsane@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hashem Hashempour
Street address
Central building of Shiraz university of medical sciences, Zand St
City
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Province
Fars
Postal code
7134814336
Phone
+98 71 3235 7282
Email
hashempurm@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
Shiraz University of Medical Sciences
Position
Master's degree student
Latest degree
Bachelor
Other areas of specialty/work
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Phone
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Person responsible for updating data

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Full name of responsible person
Sara Bashiri
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Master's degree student
Latest degree
Bachelor
Other areas of specialty/work
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Postal code
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Email
bashiriisara@gmail.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