Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Investigation of the effect of N-acetylcysteine on serum liver enzymes and metabolic profiles in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Determination of the effect of N-acetylcysteine on serum levels of liver enzymes and metabolic profiles in patients with non-alcoholic fatty liver disease

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 74 patients

Settings and conduct
The study will be performed in the gastrointestinal clinic of Shahid Beheshti Hospital affiliated to Kashan University of Medical Sciences.Study participants were randomly assigned to receive N-acetylcysteine or placebo for 8 weeks. In addition, the tablets are provided to patients with separate codes 1 and 2 in order to blind the researchers and study participants by a trained expert.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Patients with non-alcoholic fatty liver disease based on diagnostic criteria.2. age 25 -75 years. 3. Non-smoking Criteria for exclusion from the study: 1. Unwillingness to cooperate 2. Suffering from any acute and active infection. 3. Consumption of any type of supplement (vitamins, minerals, etc.) by the patient during the last 3 months. 4. Severe kidney failure (eGFR less than 30 ml / min) 5. Severe hepatic impairment 6. Diabetes mellitus 7. Hyperlipidemia requires drug treatment

Intervention groups
patients with non-alcoholic fatty liver disease are identified based on diagnostic criteria and then randomly divided to receive N-acetylcysteine or placebo for 8 weeks.

Main outcome variables
Insulin resistance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201220049772N1**
Registration date: **2021-02-20, 1399/12/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-20, 1399/12/02**
Update count: **0**

Registration date
2021-02-20, 1399/12/02

Registrant information

Name
Mehrdad Sinaeinejhad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5554 0026

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mehrdad.sinaeinejhad@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01

Expected recruitment end date
2021-06-15, 1400/03/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effect of N-acetylcysteine on serum liver enzymes and metabolic profiles in patients with non-alcoholic fatty liver disease

Public title
.Effect of N-acetylcysteeine on non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with non-alcoholic fatty liver disease based on diagnostic criteria Age 25 to 75 years No smoking
Exclusion criteria:
Having any acute and active infection Consumption of any kind of supplement (vitamins, minerals, etc.) by the patient during the last 3 months Severe renal failure (eGFR less than 30 ml / min) Severe liver failure Diabet mellitus Hyperlipidemia requires medical treatment
Age
From **25 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
The tablets are identified by a trained expert with separate codes 1 and 2 in order to blind the researchers and study participants. Patients are coded from 1 to 74 based on the time of referral to the gastroenterology clinic. 37 numbers are extracted by a table of random numbers and They form a group. The next 37 numbers extracted from the table of random numbers are placed in another group. In the end, each drug code is assigned to a group
Blinding (investigator's opinion)
Double blinded
Blinding description
The tablets are provided to patients with separate codes 1 and 2 in order to blind the researchers and study participants by a trained expert.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kashan University of Medical Sciences
Street address
Shahid beheshti hospital., Ghotb ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
87159/81151
Approval date
2020-12-20, 1399/09/30
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.150

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver_N acetyle cysteine
ICD-10 code
ICD-10 code description
Non-alcoholic fatty liver

Primary outcomes

1

Description
Primary outcome variables in this study include insulin resistance
Timepoint
Calculation of insulin resistance at the beginning of the study and eight weeks after starting N acetylcysteine
Method of measurement
The Index-HOMA formula is used to calculate insulin resistance, which is the product of serum insulin (ml /µIU) multiplied by fasting plasma glucose (dL / mg) divided by 405.

Secondary outcomes

1

Description
Serum levels of liver enzymes
Timepoint
At the beginning of the study and eight weeks after starting to take N-acetylcysteine
Method of measurement
Enzymatically using an autoanalyzer

2

Description
Metabolic profiles (fasting plasma glucose, fasting serum cholesterol, fasting serum triglyceride)
Timepoint
At the beginning of the study and eight weeks after starting to take N-acetylcysteine
Method of measurement

Serum total cholesterol, C-LDL, C-HDL and triglyceride concentrations are measured enzymatically using an autoanalyzer. Determination of fasting blood sugar using glucose oxidase / peroxidase method Pars Azmoun Company, Tehran, Iran)

Intervention groups

1

Description
Intervention group: In this study, N-acetylcysteine tablets made by Osweh Company with a dose of 600 mg, 3 tablets for 8 weeks of intervention will be used.
Category
Treatment - Drugs

2

Description
Control group: In this study, placebo tablets, which are exactly the same shape and size as N-acetylcysteine tablets and made by Osweh company, will be used in the amount of three tablets daily for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gastroenterology Clinic of Shahid Beheshti Hospital, Kashan
Full name of responsible person
Mehrdad sinaeinejhad
Street address
Ghotb ravandi blvd, Shahid beheshti hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Hamidreza banafshe
Street address
Vice Chancellor for Research and Technology of Kashan University of Medical Sciences,Ghotb ravandi blvd
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Web page address
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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
Kashan 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
Kashan University of Medical Sciences
Full name of responsible person
Sinaeinejhad mehrdad
Position
Medical resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Position
Internal medical resident

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Person responsible for updating data

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Position
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Medical doctor

Other areas of specialty/work
Internal Medicine

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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
Information about the main outcome and secondary consequences can be shared

When the data will become available and for how long
Start the access period immediately after printing the results

To whom data/document is available
Physicians and researchers working in academic and scientific institutions

Under which criteria data/document could be used
Any use of the documents must be with the permission of the researchers

From where data/document is obtainable
Dr. Abbas Arj; Address: Ghotb ravandi blvd, Shahid Beheshti Hospital, Postal Code: 87159/81151 Dr. Mohsen Razavizadeh; Address: Ghotb ravandi blvd, Shahid Beheshti Hospital, Postal Code: 87159/81151

What processes are involved for a request to access data/document
After receiving a written request from the applicant with the mentioned conditions, and his identity verification, the documents will reach him within a maximum of one month.

Comments