

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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)

Phone

+98 31 5554 0026

Email address

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-acetylcysteine 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

Isfahan

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

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Ghotb ravandi blvd, Shahid beheshti hospital

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beheshtihospital@kaums.ac.ir

Web page address

http://beheshti.kaums.ac.ir

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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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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Latest degree

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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