Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy of N-Acetylcysteine in Improving Clinical and Biochemical Parameters of Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) in Children and Adolescents: A double-blind, placebo-controlled clinical trial study

Protocol summary

Study aim

To determine and evaluate the effectiveness of N-acetylcysteine in improving clinical, biochemical, and metabolic indices in children and adolescents with metabolic dysfunction-associated fatty liver disease (MASLD)

Design

A controlled, parallel-group, randomized, phase 3, double-blind clinical trial on 64 children and adolescents with MASLD. Random allocation will be by stratified randomization using a randomized block design (permuted block randomization) with 8 octoploid blocks.

Settings and conduct

This study will be conducted in Children's Medical Center hospitals on 64 children and adolescents with MASLD. The study will be conducted in a double-blind manner with a control group. Given the double-blind nature of the study, the sets of cans containing capsules will be prepared by someone other than the researcher before the study begins, and the placebo will also be similar in appearance to the intervention group. The intervention group will receive daily N-acetylcysteine , and the control group will receive placebo for 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Overweight and obese pediatrics, having a Z score of body mass index higher than 1 and less than 3 for age and sex, Diagnosis of metabolic dysfunction-associated fatty liver disease by a specialist. Exclusion criteria: chronic disease, intake of medications or supplements that affect appetite, weight or metabolism at least 6 months before the study.

Intervention groups

The intervention group will receive N-acetylcysteine at a dose of 70 mg/kg/day and ursodeoxycholic acid at a dose of 10–15 mg/kg/day for 12 weeks. The control group will receive maltodextrin as a placebo, completely identical to the intervention group, and ursodeoxycholic acid at a dose similar to the intervention group.

Main outcome variables

Liver enzymes, BMI, lipid profile and glycemic factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220409054467N7**
Registration date: **2026-08-08, 1405/05/17**
Registration timing: **prospective**

Last update: **2026-08-08, 1405/05/17**
Update count: **0**

Registration date

2026-08-08, 1405/05/17

Registrant information

Name

Pejman Rohani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6694 1417

Email address

rohanipejmanmd@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-13, 1405/05/22

Expected recruitment end date

2027-02-06, 1405/11/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of N-Acetylcysteine in Improving Clinical and Biochemical Parameters of Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) in Children and Adolescents: A double-blind, placebo-controlled clinical trial study

Public title

Efficacy of N-Acetylcysteine in Improving Clinical and Biochemical Parameters of Metabolic Dysfunction-Associated Steatotic Liver Disease in Children and Adolescents

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to cooperate and sign the informed consent form after full knowledge of the objectives and methods of the study. Girls and boys aged 7 to 18 years. Having a Z score of body mass index higher than 1 and less than 3 for age and sex. Diagnosis of MASLD based on imaging findings and metabolic criteria

Exclusion criteria:

Other diseases and chronic and acute liver disorders (hepatitis B, C, etc.), biliary disease, known autoimmune diseasesو and inherited disorders affecting the liver (iron, copper, etc.). History of alcohol consumption or alcohol consumption more than 10 grams per day in women and more than 20 grams per day in men. Pregnancy or breastfeeding in women Take hepatotoxic drugs such as phenytoin, amoxifen, and lithium celiac disease, diabetes, cardiovascular disease, lung disease, and kidney disease Substance abuse, chronic inflammatory disease, history of cancer, hormone therapy, recent weight loss diet. Consume St. John's wort, omega 3, coenzyme Q10, and carnitine Take medications or supplements that affect appetite, weight, or metabolism for at least 6 months before the study (such as medications that affect carbohydrate, protein, or fat metabolism, and medications that reduce or increase appetite or food intake, including herbal supplements).

Age

From **7 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be used as Stratified Randomization using the Permuted block randomization method with quadruple and eight blocks. According to the sample size of 64 that has been determined, 8 octoploid blocks will be produced using the online site (www.sealedenvelope.com).In the Stratified Randomization method, age and BMI will be used as layers. subjects in each strata will be assigned to treatment or placebo group based on a random list produced by the online site (www.sealedenvelope.com). The random list containing 3-digit codes for each patient that identifies the relevant treatment will be provided to the researcher and will be inserted on the labels of 64 drug bottles. Randomization and blinding of the study are performed to maintain concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. The participants will be divided into 2 groups receiving N-Acetylcysteine and the group receiving placebo. Given the double-blind nature of the study, before the study begins, the sets of cans containing the N-Acetylcysteine supplement will be prepared by someone other than the researcher, and the placebo will also be similar in appearance to the N-Acetylcysteine, so that neither the researcher nor the participant will be aware of the type of treatments received by each group. In addition, during the evaluation of the desired outcomes, the researcher will be unaware of the allocation of participants to each group (intervention and control groups) until after the end of the intervention period.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Digestive Diseases Research Institute- Tehran University of Medical Sc

Street address

Digestive Diseases Research Institute, Shariati Hospital, Jalal Al-Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713014

Approval date

2026-07-25, 1405/05/03

Ethics committee reference number

IR.TUMS.DDRI.REC.1405.019

Health conditions studied

1

Description of health condition studied

Metabolic Dysfunction-Associated Steatotic Liver Disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Disease severity index

Timepoint

Beginning and end of the study

Method of measurement

Liver ultrasound

2

Description

Serum Alanine Aminotransferase (ALT) levels

Timepoint

Beginning and end of the study

Method of measurement

Laboratory kit

3

Description

Serum Aspartate Aminotransferase (AST)levels

Timepoint

Beginning and end of the study

Method of measurement

Laboratory kit

Secondary outcomes

1

Description

Body mass index

Timepoint

Beginning and end of the study

Method of measurement

Divide weight in kilograms by height in meters squared

2

Description

Serum glucose levels

Timepoint

Beginning and end of the study

Method of measurement

Laboratory kit

3

Description

Serum triglyceride level

Timepoint

Beginning and end of the study

Method of measurement

Laboratory kit

Intervention groups

1

Description

Intervention group: In this group, individuals take daily N-acetylcysteine at a dose of 70 Milligrams per kilogram of body weight per day in two divided doses, as well as Ursodeoxycholic Acid at a dose of 10–15 Milligrams per kilogram of body weight per day in two divided doses (maximum 1000 Milligrams per day). The drug is supplied by Actover Company.

Category

Treatment - Drugs

2

Description

Control group: In the control group, in addition to ursodeoxycholic acid at the same dose as the intervention group, participants will be given a placebo that is completely identical to the original drug. The placebo is provided by Actover.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

MohammadHassan Sohouli

Street address

Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran

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cmcpr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ramin Kordi

Street address
Tehran University of Medical Sciences, Keshavarz Blvd, Tehran, Iran.

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Pejman Rohani

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Pejman Rohani

Position
Associate professor

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Person responsible for updating data

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Name of organization / entity
Tehran University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available