Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Oct 2026

Evaluation of allopurinol efficacy in patients with nonalcoholic fatty liver disease: a randomized, double blind, placebo-controlled trial

Protocol summary

Study aim

Evaluation of the effect of allopurinol on liver steatosis, insulin resistance, systemic inflammation, oxidative stress, lipid profile, liver enzymes and anthropometric measurements in patients with non-alcoholic fatty liver disease compared to placebo

Design

In this phase III clinical trial, 44 eligible patients are enrolled. patients are randomly assigned in a 1 to 1 ratio to allopurinol or placebo groups. Randomization is performed online based on the blocked randomization method. The person who dose not play a role in checking in the inclusion criteria and intervention, assigns subjects to the groups according to the created codes.

Settings and conduct

This study is done on eligible patients with nonalcoholic fatty liver disease referred to the gastroenterology clinic. After obtaining informed consent, patients are invited for laboratory tests, computed tomography and anthropometric measurements. Patients are also requested to complete forms related to 24-hour dietary recall and physical activity. Patients are randomly assigned to either allopurinol or placebo groups. The person who does not play a role in intervention and is unaware of the allocation of patients , packs medications based on the created codes online. Then the medications are delivered to patients according to these codes. This randomization and assignment remain hidden from researchers and participants, until the completion of statistical analysis. After completing the 4-month intervention period, patients are invited to carry out assessed variables at the beginning of the study.

Participants/Inclusion and exclusion criteria

Entry requirements: age between 18 and 70 years; not having history of alcohol consumption; lack of other liver diseases; the levels of aminotransferases should not exceed 2.5 times the upper limit of normal; no previous allergy to allopurinol; not having chronic kidney disease (definedas an estimated glomerular filtration rate <60 mL/min/1.73m2); serum uric acid levels greater than 4 mg/dl for men and more than 3 mg/dl for women; for diabetic patients, hemoglobin A1c should be less than 8% and the dose of antidiabetic drugs should be constant for at least 3 months; not having hematological disorders; not having kidney stones. Conditions of failure to enter: pregnancy and lactation; use of drugs interact with allopurinol; taking hepatotoxic drugs; occurrence of allergic reaction due to allopurinol intake.

Intervention groups

Intervention group: Allopurinol 300 mg once daily for 4 months. Control group: Placebo once a day for 4 months.

Main outcome variables

In this study, the efficacy of allopurinol on the improving liver steatosis (assessed by computed tomography), insulin resistance (assessed by the homeostasis model), systemic inflammation, oxidative stress, lipid profile, liver enzymes and anthropometric measurements in patients with non-alcoholic fatty liver disease compared to placebo, is determined.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160920029889N1**
Registration date: **2018-01-09, 1396/10/19**
Registration timing: **prospective**

Last update: **2018-01-09, 1396/10/19**
Update count: **0**

Registration date

2018-01-09, 1396/10/19

Registrant information

Name

Afshin Shiva

Name of organization / entity

Urmia University of Medical Sciences

Country
Iran (Islamic Republic of)
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Email address
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2018-02-20, 1396/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of allopurinol efficacy in patients with nonalcoholic fatty liver disease: a randomized, double blind, placebo-controlled trial

Public title
Evaluation of allopurinol efficacy in patients with nonalcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 and 70 years Not having history of alcohol consumption Lack of other liver diseases The levels of aminotransferases should not exceed 2.5 times the upper limit of normal No previous allergy to allopurinol Not having chronic kidney disease (definedas an estimated glomerular filtration rate <60 mL/min/1.73m2) Serum uric acid levels greater than 4 mg/dl for men and more than 3 mg/dl for women For diabetic patients, hemoglobin A1c should be less than 8% and the dose of antidiabetic drugs should be constant for at least 3 months Not having hematological disorders Not having kidney stones
Exclusion criteria:
Pregnancy and lactation Use of drugs interact with allopurinol (including didanosine, angiotensin-converting enzyme inhibitors, antacids (except sodium bicarbonate), azathioprine, mercaptopurine, vitamin K antagonists (including warfarin and other coumarin derivatives)) Taking hepatotoxic drugs (including calcium channel blockers, high doses of synthetic estrogens, methotrexate, amiodarone, chloroquine) Occurrence of allergic reaction due to allopurinol intake
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
The blocked randomization method; online; by creating the random blocks of 4 and 6 subjects and unique randomization codes; by the person who does not play a role in intervention and checking inclusion criteria
Blinding (investigator's opinion)
Double blinded
Blinding description
A person who is not involved in intervention and is unaware of the randomization and allocation of patients, packs medications based on randomization codes.Drugs are delivered to the patients according to the codes. Participants, health care personnel, researcher, evaluators of the outcome and data analyzer are blind. This blindness remains hidden until statistical analysis completes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Orjhans Street, Resalat Blvd, Urmia
City
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Province
West Azarbaijan
Postal code
5714783734
Approval date
2017-02-08, 1395/11/20
Ethics committee reference number
IR.UMSU.REC.1395.476

Health conditions studied

1

Description of health condition studied
nonalcoholic fatty liver disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
change in liver steatosis
Timepoint
before the intervention and at the end of the study
Method of measurement
abdominal computed tomography scans-no contrast injection-spiral (liver hounsfield unit and the liver attenuation index (liver hounsfield unit minus spleen hounsfield unit))

2

Description
change in systemic inflammation
Timepoint
before the intervention and at the end of the study
Method of measurement
high sensitivity c-reactive protein

Secondary outcomes

1

Description
change in insulin resistance
Timepoint
before the intervention and at the end of the study
Method of measurement
homeostasis model assessment of insulin resistance

2

Description
change in oxidative stress
Timepoint
before the intervention and at the end of the study
Method of measurement
malondialdehyde

3

Description
change in lipid profile
Timepoint
before the intervention and at the end of the study
Method of measurement
triglycerides, total cholesterol, high density lipoprotein, low density lipoprotein

4

Description
change in liver enzymes
Timepoint
before the intervention and at the end of the study
Method of measurement
alanine aminotransferase, aspartate aminotransferase

5

Description
change in anthropometric measurements
Timepoint
before the intervention and at the end of the study
Method of measurement
weight, body mass index, waist circumference, hip circumference, waist to hip ratio

Intervention groups

1

Description
Intervention group: reception of allopurinol 300 mg (manufacturing Ramopharmin Pharmaceutical Company) once a day, for 4 months
Category
Treatment - Drugs

2

Description
Control group: reception of placebo (manufacturing faculty of pharmacy) once a day, for 4 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani hospital
Full name of responsible person
Afshin Shiva
Street address
Ayatollah Taleghani Hospital, Kashani St., Urmia
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2

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Afshin Shiva
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Clinical pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Individual participant data - All data is shared. Study protocol- The entire protocol is shared. Statistical analysis scheme- The whole scheme is shared. Consent Form Conscious- All parts of the form are shared. Clinical study report- All clinical reports are shared.
When the data will become available and for how long
Start the access period: 8 months after printing results- Access time interval: Unlimited
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
To conduct systematic review and meta-analysis
From where data/document is obtainable
1- Dr. Afshin Shiva, shiva@umsu.ac.ir 2- Dr. Sepideh Ahadi, sepidehahadi21@ymail.com
What processes are involved for a request to access data/document
The data will be available 8 months after the results are printed. The applicant can receive data by emailing the request in less than one month.
Comments