Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of allopurinol in preventing liver fibrosis in non-alcoholic fatty liver disease: A Randomized Placebo-Controlled Clinical Trial

Protocol summary

Study aim
The effect of allopurinol in preventing liver fibrosis in non-alcoholic fatty liver disease

Design
Phase 3 randomized clinical trial on 154 patients with control and intervention groups will be 1:1 parallel to the Permuted Block Randomization method and will be double-blind. Random numbers, determination of random blocks and random assignment to groups will be done with Excel software .

Settings and conduct
Imam Reza Hospital A double-blind study of drug prescribers, patients and data collectors

Participants/Inclusion and exclusion criteria
Inclusion criteria: age of 18-70 years, no history of alcohol consumption, no other liver diseases (based on the history taken by the doctor at the beginning of the visit, if other underlying liver diseases are suspected, the patient is undergoing immunological tests In terms of viral markers, autoimmune and tumor markers, and biochemistry are used to diagnose viral hepatitis, autoimmune hepatitis, hematochromatosis, Wilson's disease and alpha-antitrypsin deficiency, and in case of these cases, the patient will not be included in the study). Previous sensitivity to allopurinol, in the case of diabetic patients, HbA1c (glycosylated hemoglobin) less than 7% and stable antidiabetic drug dosage for at least the last 3 months until the study entry.

Intervention groups
Administration of allopurinol 300 mg, once a day for 12 weeks

Main outcome variables
hs-CRP (C-Reactive Protein High-Sensitivity), MDA (Malondialdehyde), TAC (Total antioxidant capacity), FIB-4 (four factor fibrosis score)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170609034406N12**
Registration date: **2024-09-26, 1403/07/05**
Registration timing: **prospective**

Last update: **2024-09-26, 1403/07/05**
Update count: **0**

Registration date
2024-09-26, 1403/07/05

Registrant information

Name
Afshin Gharekhani

Name of organization / entity
Faculty of Pharmacy/Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 3334 1315

Email address
gharekhania@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-21, 1403/09/01

Expected recruitment end date
2025-11-22, 1404/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of allopurinol in preventing liver fibrosis in

non-alcoholic fatty liver disease: A Randomized Placebo-Controlled Clinical Trial

Public title
The effect of allopurinol in preventing liver fibrosis in non-alcoholic fatty liver disease
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-70 years No history of alcohol consumption Absence of other liver diseases No previous allergy to allopurinol In the case of diabetic patients, HbA1c (glycosylated hemoglobin) is less than 7% and the dose of antidiabetic medication has been stable for at least the last 3 months until the time of study entry.
Exclusion criteria:
Pregnancy and breastfeeding Serum creatinine more than 1.5 mg/dl Simultaneous use of drugs that interact with allopurinol Simultaneous use of drugs that cause hepatic steatosis Simultaneous use of research drugs effective on non-alcoholic fatty liver disease
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: **154**
More than 1 sample in each individual
Number of samples in each individual: **2**
Blood and Serum
Randomization (investigator's opinion)
Randomized
Randomization description
Online randomization and permuted block randomization will be done, and in this way, random sequences with specific codes will be created.
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the double-blind nature of this study, a person who has no role in the intervention and checking the entry and exit criteria will perform the randomization online and assign the patients to the groups based on the random sequence created. Another person, who has no role in the intervention and is unaware of the allocation of patients, will package the drugs based on the codes. This randomization and assignment of codes remains hidden from the researchers and participants until the statistical analysis is completed.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Faculty of Pharmacy - Tabriz University of Medical Science
Street address
Research Ethics Committees , 4th floor, Faculty of Pharmacy, Tabriz University of Medical Sciences, Attar Neishaburi, Golgasht St, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5766414766
Approval date
2024-09-17, 1403/06/27
Ethics committee reference number
IR.TBZMED.REC.1403.475

Health conditions studied

1

Description of health condition studied
Liver fibrosis in non-alcoholic fatty liver disease
ICD-10 code
K74
ICD-10 code description
Fibrosis and cirrhosis of liver

Primary outcomes

1

Description
Serum hs-CRP (C-Reactive Protein High-Sensitivity) level
Timepoint
At the beginning and end of the study
Method of measurement
ELISA Kit

2

Description
MDA (Malondialdehyde) level in serum
Timepoint
At the beginning and end of the study
Method of measurement
(MDA) Lipid Peroxidation Kit

3

Description
Total antioxidant capacity (TAC) level in serum
Timepoint
At the beginning and end of the study
Method of measurement
Total Antioxidant Capacity Kit

4

Description
FIB-4 non-invasive score
Timepoint
At the beginning and end of the study
Method of measurement
FIB-4: (Age [yr] x AST) / ((PLT [10(9)/L]) x (□ALT□^(1/2)))

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: (Allopurinol + standard non-alcoholic fatty liver treatment): 77 patients will be included in the study based on inclusion and exclusion criteria and will receive 300 mg allopurinol once a day for 12 weeks along with standard treatments.
Category
Prevention

2

Description
Control group: (receive placebo + standard non-alcoholic fatty liver treatment): 77 patients will be included in the study based on the entry and exit criteria and will receive a placebo equal to 300 mg of allopurinol once a day for 12 weeks along with standard treatments.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Afshin Gharekhaniit
Street address
Imam Reza General Hospital , Across from Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3334 7054
Email
gharekhania@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Parviz Shahabi
Street address
No 2 central building, Tabriz University of Medical Science, Golgasht Street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5147663419
Phone
+98 41 3334 4280
Email
shahabip@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Afshin Gharekhani
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address

No 2 central building, Tabriz University of Medical Science, Golgasht Street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Phone
0098413372250

Email
gharekhania@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Afshin Gharekhani

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

Street address
No 2 central building, Tabriz University of Medical Science, Golgasht Street, Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5166614766

Phone
+98 41 3337 2250

Email
gharekhania@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Sama Samankan

Position
Clinical pharmacy student

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

Street address
Faculty of Pharmacy , Tabriz University of Medical Science, Daneshgah Street, Tabriz,Iran

City
Tabriz

Province
East Azarbaijan

Postal code
5147663419

Phone
+98 41 3333 7244

Email
samankan@tbzmed.ac.ir

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 further information.

Study Protocol
No - There is not 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