Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

study the effects of Allopurinol on liver enzymes and grade of fatty liver on ultrasound in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Analysis of the effect of allopurinol on AST and ALT in patients with non-alcoholic fatty liver disease

Design
Randomized Control trials, double blind

Settings and conduct
This study will be conducted on patients with non-alcoholic fatty liver disease who are referred to the Center for Applied Scientific Research and after receiving their consent. The intervention group will receive 100 mg Allopurinol for 6 months on an daily basis. Blood samples will be taken from all of the subjects participating in the study at the start of the study, 3 months after the start of the study and at the end of the study to measure the level of liver enzymes. Also at this interval, patients will be screened for ultrasound examination of fatty liver gradients. Measurement of the level of liver enzymes will be taken part in the Danesh lab and performance of ultrasound in the Tabesh imaging center.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients who have been diagnosed with non-alcohol fatty liver based on ultrasound evidence and tests; Patients aged 18-65 years: patients whom have non-symptomatic hyperuricemia (serum uric acid >7 mg/dl for men and >6.5 mg/dl for women); Exclusion criteria: pregnancy and lactation; allergy to Allopurinol or its contents; use of alcohol; patients with renal deficiency with creatinine clearance (GFR) <30 mg/ml; simultaneous use of drugs which have interaction with Allopurinol (mercaptopurine, azathioprine, ...); patients who have had gout or who are using uricosuric agents or thiazide diuretics.

Intervention groups
the case group will receive 100 mg allopurinol daily whereas the cntrol group will receive nothing.

Main outcome variables
Liver Enzymes (AST; ALT); ultrasound grade

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180404039187N2**
Registration date: **2018-11-23, 1397/09/02**
Registration timing: **retrospective**

Last update: **2018-11-23, 1397/09/02**
Update count: **0**

Registration date
2018-11-23, 1397/09/02

Registrant information

Name
Elnaz Shaseb

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 1337 2250

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shasebe@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-01-23, 1395/11/04

Expected recruitment end date
2018-04-24, 1397/02/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

study the effects of Allopurinol on liver enzymes and grade of fatty liver on ultrasound in patients with non-alcoholic fatty liver disease

Public title
study the effects of allopurinol in patients with non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients whom have non-alcoholic fatty liver disease based on the ultrasound and laboratory tests patients whom have non-symptomatic hyperuricemia (serum uric acid >7 mg/dl for men and >6.5 mg/dl for women)
Exclusion criteria:
pregnancy and lactation allergy to Allopurinol or its contents use of alcohol patients with renal deficiency with creatinine clearance (GFR) <30 mg/ml simultaneous use of drugs which have interaction with Allopurinol (mercaptopurine, azathioprine, ...) patients who have had gout or who are using uricosuric agents or thiazide diuretics
Age
From **18 years** old to **65 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: **100**
More than 1 sample in each individual
Number of samples in each individual: **2**
Blood sampling and Ultrasound
Randomization (investigator's opinion)
Randomized
Randomization description
Arrange the accident stages: 1) Determine the volume of each block (Foursquare blocks) 2) Prepare block lists and assign numbers to them AABB(1) ABAB(2) ABBA(3) BBAA(4) BABA(5) BAAB(6) 3) Selection of random numbers between 1 and 6 4) Identification of the Treatment Assignment For example: AABB(1)_BBAA(4)_ABAB(2)_BABA(5)
Blinding (investigator's opinion)
Double blinded
Blinding description
Double blind: People in the study (participants) and observers (researchers) who include researchers, clinical caregivers and physicians, assess and analyze data, and other care and treatment personnel do not know who and in which group they are during the study
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2018-09-25, 1397/07/03
Ethics committee reference number
IR.TBZMED.REC.1397.546

Health conditions studied

1

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

Primary outcomes

1

Description
serum liver enzymes AST and ALT and grade of fatty liver based on ultrasound
Timepoint
at the beginning and 3 and 6 months later
Method of measurement
laboratory tests and ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: consumption of 100 mg Allopurinol daily for 6 months
Category
Treatment - Drugs

2

Description
Control group: routin care
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Teaching Hospital of Tabriz
Full name of responsible person
Manuchehr khoshbaten MD
Street address
Golgasht, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Sanaz Hamedyazdan MD
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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
Tabriz University of Medical Sciences
Proportion provided by this source
30
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
Dr Elnaz Shaseb
Position
Member of the faculty of clinical pharmacy
Latest degree
Ph.D.
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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