

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 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)

Phone

+98 41 1337 2250

Email address

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		Assignment Parallel	
		Other design features	
Public title	study the effects of allopurinol in patients with non-alcoholic fatty liver disease	Secondary Ids	empty
Purpose	Treatment	Ethics committees	
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	1	
Age	From 18 years old to 65 years old	Ethics committee	
Gender	Both	Name of ethics committee	Ethics Committee of Tabriz University of Medical Sciences
Phase	3	Street address	Research & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences, Golghast St, Tabriz
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor - Data analyser - Data and Safety Monitoring Board	City	Tabriz
Sample size	Target sample size: 100 More than 1 sample in each individual Number of samples in each individual: 2 Blood sampling and Ultrasound	Province	East Azarbaijan
Randomization (investigator's opinion)	Randomized	Postal code	5166614766
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)	Approval date	2018-09-25, 1397/07/03
Blinding (investigator's opinion)	Double blinded	Ethics committee reference number	IR.TBZMED.REC.1397.546
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	Health conditions studied	
Placebo	Not used	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: routine 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

City

Tabriz

Province

East Azarbaijan

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59-3347054

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+98 41 3334 7054

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Web page address

<https://imamreza.tbzmed.ac.ir/>

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

Medical Pharmacy

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Person responsible for updating data

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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