Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of mast cell stabilizers on elastographic findings of patients with nonalcoholic fatty liver disease

Protocol summary

Study aim
Effect of mast cell stabilizer on elastographic findings of patients with nonalcoholic fatty liver disease

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 50 patients. Patients were randomly divided 2 group by block randomization.

Settings and conduct
Participants will be selected from patients with non-alcoholic fatty liver disease referred to the gastrointestinal clinics of Imam Reza Hospital. General information of patients will be extracted using a questionnaire. All patients will also undergo elastography. First group will be given the drug Ketotifen 1mg twice a day for 6 months. The control group will also take a placebo drug in addition to Will receive their usual. After completing 6 months of treatment, patients will undergo elastography again and the degree of stasis and liver fibrosis will be determined based on LSM and CAP criteria. Pre- and post-intervention findings will be compared.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18 to 59 years old; no history of alcohol; do not take drugs with liver toxicity. Exclusion criteria: liver disease with specific etiologies such as viral hepatitis; Cirrhosis; pregnancy or lactation; use anti histamine or anti cholinergic; use alcohol; uncontrolled diabetes.

Intervention groups
Case group will take Ketotifen 1 mg 2 times a day for 6 months. The control group will receive starch capsules with this pattern.

Main outcome variables
Hepatic steatosis and fibrosis indices in patients with non-alcoholic fatty liver disease

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220104053626N6**
Registration date: **2023-10-19, 1402/07/27**
Registration timing: **prospective**

Last update: **2023-10-19, 1402/07/27**
Update count: **0**

Registration date
2023-10-19, 1402/07/27

Registrant information
Name
Masood Dinevari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-22, 1402/09/01
Expected recruitment end date
2024-02-20, 1402/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Effect of mast cell stabilizers on elastographic findings of patients with nonalcoholic fatty liver disease

Public title
The effect of mast cell stabilizers on non-alcoholic fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 59 years Willingness to participate in the study No history of alcohol consumption Do not take drugs with liver toxicity
Exclusion criteria:
Having liver disease with specific etiologies such as viral hepatitis Alcohol consumption Pregnancy and lactation Take other drugs anti histamine or anti cholinergic Cirrhosis of the liver Uncontrolled diabetes
Age
From **18 years** old to **59 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
From the patients who volunteered to participate in the study, 60 persons will be selected by simple random sampling. Randomization method: Randomization unit block: Individual Randomization layers: In each block, people will be matched based on age and gender. Random Allocation software: Random Allocation software How to create a random sequence: Using Random Allocation software Hide: The random sequence created is kept in a safe place and is done by an independent person who is not involved in the experiment during the study. Random allocation of hidden individuals, patients and researchers will not be aware of it.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a double-blind study in which the researcher of this study and the patients participating in the study will be unaware of the type of drugs received. drugs will be provided to patients by another person who has no role in completing the questionnaire and performing blood tests. Patients will also be informed of the existence of two types of drugs (ketotifen and placebo) when obtaining consent, but will be unaware of which study groups they will be included in. Placebo tablet are similar in appearance, color, and size to ketotifen tablet.
Placebo
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
Ethic committee,vice chancellor for research,faculty of medicine,Tabriz university of Medical sciences,Golgasht Ave,Tabriz,Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5163996889
Approval date
2023-09-18, 1402/06/27
Ethics committee reference number
IR.TBZMED.REC.1402.443

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
Hepatic steatosis elastographic index in patients with non-alcoholic fatty liver disease
Timepoint
Before and after the intervention
Method of measurement
CAP index in liver elastography

2

Description
Hepatic fibrosis elastographic index in patients with non-alcoholic fatty liver disease
Timepoint
Before and after the intervention
Method of measurement

LSM index in liver elastography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to their usual medications, Ketotifen 1mg tablets (manufactured by Alhavi pharmaceutical company) will receive 2 times a day for 6 months .
Category
Treatment - Drugs

2

Description
Control group: In addition to their usual medications, placebo tablets with the same shape and size (manufactured by Alhavi pharmaceutical company) will receive 2 times a day for 6 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Zahra Mortezapour
Street address
Emam Reza Hospital, Golgasht Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
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Vice chancellor for Research,Tabriz University of medical sciences, Golgasht Street,Tabriz
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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
50
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
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Full name of responsible person
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Position
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Other areas of specialty/work
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Person responsible for updating data

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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
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
Not applicable