

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 7054

##### Email address

dinvarim@tbzmed.ac.ir

##### 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 Alvahi 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 Alvahi 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 Morteza pour

##### Street address

Emam Reza Hospital, Golgasht Ave.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5163996889

##### Phone

+98 41 3337 2084

##### Email

Z.mortezapour1373@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Parviz Shahabi

##### Street address

Vice chancellor for Research,Tabriz University of medical sciences, Golgasht Street,Tabriz

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5164886994

#### Phone

+98 41 3337 2084

#### Email

shahabi\_p@gmail.com

#### 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Masood Faghieh Dinevari

##### Position

Assistant professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Internal Medicine

##### Street address

Internal medicine department, Emam reza hospital, Golgasht avenue, Daneshgah street

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##### Province

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

**Full name of responsible person**

Masoud Faghii Dinevari

**Position**

assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Masoud Faghii Dinevari

**Position**

Associate professor

**Latest degree**

Subspecialist

**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