

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### The effect of hepatoheal tablet on liver enzymes of patients with non alcoholic fatty liver and its comparison with vitamin E

#### Protocol summary

##### Summary

This study is a randomized double-blind and controlled drug clinical trial on 90 patients over 18 years of non-alcoholic fatty liver disease based on ultrasound will be performed. In this study, patients divided randomly in 3 groups vitamin E 400+ placebo tablet or hepatoheal tablet( herbal remedy contain Vitis vinifera and Fragaria vesca)+ placebo pearl( 2 times of a day) or daily 1 hepatoheal tablet +vitamin E pearl 400 for 4 months. Exclusion criteria included a history of other liver disease, autoimmune disease and cancer, hepatotoxic drugs, and treatments and diet for fatty liver in the past 3months , pregnancy and lactation. at the beginning and end of the study, blood levels of aminotransferases are measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014042612438N6**

Registration date: **2014-08-18, 1393/05/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-08-18, 1393/05/27

##### Registrant information

###### Name

Mohsen Taghizadeh

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1555 0021

##### Email address

taghizadeh\_m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Barij Research Center of Medicinal Herbs

##### Expected recruitment start date

2014-05-22, 1393/03/01

##### Expected recruitment end date

2016-05-21, 1395/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of hepatoheal tablet on liver enzymes of patients with non alcoholic fatty liver and its comparison with vitamin E

##### Public title

The effect of hepatoheal tablet on non alcoholic fatty liver

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria :Both sexes; age >18; fatty liver on ultra sound; 25< BMI<40 exclusion criteria :ast/alt<1; pregnancy; breast feeding; alcohol; hormonal disorders; other liver diseases; hepatotoxic drugs; diet or treatment for fatty liver in 3 month past; autoimmune diseases and cancers.

##### Age

From **18 years** old to **139 years** old

##### Gender

Both

##### Phase

2-3

### Groups that have been masked

No information

### Sample size

Target sample size: 90

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kashan University of Medical Science

##### Street address

Kashan University of Medical Science, Kashan

##### City

Kashan

##### Postal code

#### Approval date

2014-06-18, 1393/03/28

#### Ethics committee reference number

1398/1/5/29/پ

## Health conditions studied

### 1

#### Description of health condition studied

non alcoholic fatty liver

#### ICD-10 code

K76.0

#### ICD-10 code description

Nonalcoholic fatty liver disease (NAFLD)

## Primary outcomes

### 1

#### Description

ALT

#### Timepoint

beginning and end of study

#### Method of measurement

blood test

### 2

#### Description

AST

#### Timepoint

beginning and end of study

#### Method of measurement

blood test

### 3

#### Description

ALP

#### Timepoint

beginning and end of study

#### Method of measurement

blood test

## Secondary outcomes

### 1

#### Description

HOMA-IR

#### Timepoint

beginning and end of study

#### Method of measurement

blood test

## Intervention groups

### 1

#### Description

intervention:hepatoheal tablet+placebo pearl.2 times in day for 4 months.

#### Category

Treatment - Drugs

### 2

#### Description

control:vitamin E pearl+ placebo tablet.2 times in day for 4 months.

#### Category

Treatment - Drugs

### 3

#### Description

control:hepatoheal tablet+vitamin E pearl.2 times in day for 4 months.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinic of Beheshti Hospital

**Full name of responsible person**  
**Street address**  
Shahid Beheshti Hospital, Kashan  
**City**  
Kashan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Barij Research Center of Medicinal Herbs  
**Full name of responsible person**  
Miss L.Hejazi  
**Street address**  
Kashan Mashhad Ardehal Road, KM44  
**City**  
Kashan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Barij Research Center of Medicinal Herbs

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Kashan University of Medical Science  
**Full name of responsible person**  
Dr.M.Taghizadeh  
**Position**  
PHD  
**Other areas of specialty/work**  
**Street address**  
Kashan University Of Medical Science, Kashan  
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taghizadeh\_m@kaums.ac.ir  
**Web page address**

## Person responsible for scientific

## inquiries

#### Contact

**Name of organization / entity**  
Kashan University of Medical Science  
**Full name of responsible person**  
Dr Mohsen Razavizadeh  
**Position**  
Assistant Professor  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Barij Research Center of Medicinal Herbs  
**Full name of responsible person**  
M.Mahlouji  
**Position**  
Clinical Expert  
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mahnaz.mahlouji@yahoo.com  
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## Sharing plan

#### Deidentified Individual Participant Data Set (IPD)

*empty*

#### Study Protocol

*empty*

#### Statistical Analysis Plan

*empty*

#### Informed Consent Form

*empty*

#### Clinical Study Report

*empty*

#### Analytic Code

*empty*

#### Data Dictionary

*empty*