# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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 devided 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
**City**
Kashan
**Postal code**
**Phone**
+98 36 1555 0021
**Fax**
**Email**
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
**Other areas of specialty/work**
**Street address**
Kashan University of Medical Science, Kashan
**City**
Kashan
**Postal code**
**Phone**
+86 3615550026
**Fax**
**Email**
razavizadeh_m@kaums.ac.ir
**Web page address**

## 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
**Other areas of specialty/work**
**Street address**
Kashan Mashhad Ardehal Road, KM44
**City**
Kashan
**Postal code**
**Phone**
+98 86 4446 5112
**Fax**
**Email**
mahnaz.mahlouji@yahoo.com
**Web page address**

## 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*