Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Sep 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
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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
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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
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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