

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The therapeutic effects of co-administration of metformin, vitamin E and plant products contain cynara scolymus in patients with fatty liver

Protocol summary

Summary

Fatty liver is a common disease of the liver that is 20 to 40% of people living with the disease in different countries. Among the common treatments for the disease include vitamin E, metformin, pioglitazone, herbal products contain silymarin, etc. can be mentioned. However, there is still no cure for this disease has not been introduced in clinical practice. In other hand, today artichoke extract for the treatment of hyperlipidemia and liver disorders is used; But The experimental study on the performance of the plant in fatty liver disease hasn't taken place. According to the aforementioned study to determine the therapeutic effects of co-administration of metformin, vitamin E and herbal products contain cynara scolymus designed in patients with fatty liver. The study included 90 patients with non-alcoholic fatty liver that occurs will be randomly selected. Patients were divided into three groups of 30 people. Group I: metformin in combination with vitamin E, Group II: metformin plus herbal preparation containing cynara scolymus, Group III: Vitamin E along with herbal products containing cynara scolymus. For follow-up treatment of biochemical tests (including liver enzymes, fasting blood glucose, plasma cholesterol, triglyceride, ...) and ultrasound will be used. 1000 mg of metformin daily dose of vitamin E 400 IU and herbal products containing cynara scolymus 960 mg will be given.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017040429278N1**
Registration date: **2017-07-27, 1396/05/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-27, 1396/05/05

Registrant information

Name

Abbas Aghaei

Name of organization / entity

kermanshah university medicine science

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2018-03-22, 1397/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The therapeutic effects of co-administration of metformin, vitamin E and plant products contain cynara scolymus in patients with fatty liver

Public title

Effects of metformin, vitamin E and herbal products contain cynara scolymus for the treatment of fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: 1- Confirmed fatty liver disease using ultrasound, 2- High liver enzymes (ALT, AST),3-Aged between 18 and 70 years,4-The first visit is to treat fatty liver disease.Exclusion criteria included were: 1.Alcoholism, 2 Have a history of diabetes, cardiovascular disease, various cancers, diseases of the liver (hepatitis, liver failure, cirrhosis), kidney failure and gastrointestinal bleeding wound, 3. Being pregnant and breastfeeding infant,4-Not wanting to continue the study,5- BMI> 35,6.Have any allergies to medications,7-The use of any supplement (including herbal supplements) and vitamins such as vitamin A, H, B (2,6,12 and complex), C, D).

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

No central registration

Secondary trial Id

0000

Registration date

1999-11-30, 1378/09/09

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics Committee of Kermanshah University of Medical Sciences

Street address

kermanshah shahid beheshti BLVice Chancellor for Research and Technology Kermanshah University of Medical Sciences

City

Kermanshah

Postal code**Approval date**

2016-09-28, 1395/07/07

Ethics committee reference number

kums.rec.1395.367

Health conditions studied**1****Description of health condition studied**

fatty liver

ICD-10 code

K75.8

ICD-10 code description

(Nonalcoholic steatohepatitis (NASH

Primary outcomes**1****Description**

Liver enzymes

Timepoint

3 months after the intervention

Method of measurement

Using the Spectrophotometer IU/L

2**Description**

LDL Cholesterol

Timepoint

Three months after the intervention

Method of measurement

using a spectrophotometer mg / dl

3**Description**

HDL Cholesterol

Timepoint

Three months after the intervention

Method of measurement

using a spectrophotometer mg/dl

4**Description**

Triglyceride

Timepoint

Three months after the intervention

Method of measurement

using a spectrophotometer mg / dl

5**Description**

Fasting sugar

Timepoint

Three months after the intervention

Method of measurement

using a spectrophotometer mg / dl

6

Description

body mass index

Timepoint

Three months after the intervention

Method of measurement

Kg/m²

Secondary outcomes

1

Description

blood pressure

Timepoint

Introduction to the study and three months after the intervention

Method of measurement

Using the mercury pressure gauge

2

Description

The number of blood cells

Timepoint

Introduction to the study and three months after the intervention

Method of measurement

Using the auto blood cell counting analyzer

Intervention groups

1

Description

Metformin, 500 mg, twice a day, for three months

Category

Treatment - Drugs

2

Description

Vitamin E 400 IU, once daily, for three months

Category

Treatment - Drugs

3

Description

Artichoke herbal preparation containing 320 mg three times a day, for three days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

emam khomini hospital

Full name of responsible person

touraj ahmadi-jouybari

Street address

kermanshah,naghlie ST, emam khomini hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology

Kermanshah University of Medical Sciences

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Vice Chancellor for Research and Technology Kermanshah University of

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City

kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research and Technology

Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences

Full name of responsible person

mohammad bagher majnooni

Position

pharm D/researcher

Other areas of specialty/work

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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