Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 univercity medicine science
Country
Iran (Islamic Republic of)
Phone
+98 83 3727 2049
Email address
aghaei.a@sbmu.ac.ir

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 BLVVice 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 presure
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
City
kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology Kermanshah University of Medical Sciences
Full name of responsible person
touraj ahmadi_jouybari
Street address
kermanshah shahid beheshti BLVVice Chancellor for Research and Technology Kermanshah University of Medical Sciences
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
Street address
kermanshah, parastar BLV,Kermanshah University of Medical Sciences
City
kermanshah
Postal code
Phone
+98 83 3835 8239
Fax

Email
bagher_1985@yahoo.comdr.ahmadi_jouybari@yahoo.comaghaei.a@sbmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
touraj ahmadi_jouybari
Position
Associate Professor
Other areas of specialty/work
Street address
kermanshah shahid beheshti BLVVice Chancellor for Research and Technology Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Phone
+98 83 3835 8258
Fax
Email
bagher_1985@yahoo.comdr.ahmadi_jouybari@yahoo.comaghaei.a@sbmu.ac.ir
Web page address

Person responsible for updating data

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
Street address
kermanshah, parastar BLV,Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Phone
+98 83 3835 8239
Fax
+98 83 3835 8239
Email
bagher_1985@yahoo.comdr.ahmadi_jouybari@yahoo.comaghaei.a@sbmu.ac.ir
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