Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

The effect of Cynara scolymus L.on fatty liver indices

Protocol summary

Study aim
The herbal tea of Artichoke has a therapeutic effect on fatty liver disease.

Design
This study was done to investigate the effect of drinking of Cynara scolymus L. (Artichoke) herbal tea on the levels of AST, ALT and liver parenchyma echogenicity of 60 patients (40 women and 20 men), aged from 25 to 63 years old in Hamedan city, Iran. The blood enzymes assay and liver sonography were performed after clinical diagnosis and after treatment. Studied people were divided based on the ultrasound criterion for fatty liver disease as follows: mild (5 patients) as grade1, moderate (8 patients) as grade2 and severe (2 patients) as grade3

Settings and conduct
Hamedan Imam Khomeini Clinic. In this study, blindness has not been performed and this study is done based on the pre-medicine and post-medicine method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 30-65 years old; Detection of Non-alcoholic Fatty Liver based on high levels of ALT and AST enzymes. Ultrasound diagnosis of Fatty Liver. BMI was more than 25. People who did not Use Antioxidant complementary during a month before sampling. People who had not underlying diseases like heart acute disease, kidney, infections, diabetes, hepatitis B or C and other diseases of the liver. Not having a severe weight losing or gaining regimens within 3 months before sampling. No using of effective drugs on weight during 3 months prior to sampling. Not using drugs that are likely to be related to this disease (methotrexate, amiodarone, tamoxifen, corticosteroids, valproic acid). Exclusion criteria: Pregnancy and lactation; alcohol drinking; other liver diseases; Diet or treatment for fatty liver in the last 3 months; autoimmune diseases and cancer Reluctance to continue research.

Intervention groups
Chopped leaves of dried Artichoke- it is used twice a day (fasting in the morning and at night before bedtime) for 45 days. Brewing a tablespoon of leaf with a boiling cup (like tea) for 20 minutes on an indirect heat at 80 °C.

Main outcome variables
Liver enzymes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130126012278N3**
Registration date: **2018-02-21, 1396/12/02**
Registration timing: **retrospective**

Last update: **2018-02-21, 1396/12/02**
Update count: **0**

Registration date
2018-02-21, 1396/12/02

Registrant information

Name
Mosen Rajabi

Name of organization / entity
Applied Scientific University of Jihad-Agriculture

Country
Iran (Islamic Republic of)

Phone
+98 81 3437 3587

Email address
m.rajabi@areo.ir

Recruitment status
Recruitment complete

Funding source
Hamedan Agricultural and Natural Resources Research and Education Center

Expected recruitment start date
2017-12-06, 1396/09/15

Expected recruitment end date
2018-06-05, 1397/03/15

Actual recruitment start date
2017-06-22, 1396/04/01

Actual recruitment end date
2017-08-23, 1396/06/01
Trial completion date
empty

Scientific title
The effect of Cynara scolymus L.on fatty liver indices

Public title
The effect of Artichoke on fatty liver indices
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
30-65 years old Detection of Non-alcoholic Fatty Liver based on high levels of ALT and AST enzymes Ultrasound diagnosis of Fatty Liver BMI was more than 25 People who did not Use Antioxidant complementary during a month before sampling People who had not underlying diseases like heart acute disease, kidney, infections, diabetes, hepatitis B or C and other diseases of the liver Not having a severe weight losing or gaining regimens within 3 months before sampling Not using of effective drugs on weight during 3 months prior to sampling Not using drugs that are likely to be related to this disease (methotrexate, amiodarone, tamoxifen, corticosteroids, valproic acid)
Exclusion criteria:
Pregnancy and lactation Alcohol drinking other liver diseases Diet or treatment for fatty liver in the last 3 months Autoimmune diseases and cancer Reluctance to continue research
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Actual sample size reached: **60**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamedan University of Medical Science
Street address
Shahid Fahmideh Street, Hamedan University of Medical Science,
City
Hamedan
Province
Hamadan
Postal code
6517838678
Approval date
2014-12-24, 1393/10/03
Ethics committee reference number
16/35/9/4785/پ

Health conditions studied

1

Description of health condition studied
Non alcoholic Fatty Liver
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Liver enzymes
Timepoint
At the beginning of study, 48 hours after the end of the study (this study will take 7 weeks).
Method of measurement
blood assay results (including AST and ALT)

Secondary outcomes

1

Description
The amount of liver fat accumulation.
Timepoint
45 days
Method of measurement
Doppler color ultrasound

2

Description
Liver Enzymes
Timepoint
45 days
Method of measurement
Blood examination Results

Intervention groups

1

Description
Chopped leaves of dried Artichoke- it is used twice a day (fasting in the morning and at night before bedtime) for 45 days. Brewing a tablespoon of leaf with a boiling cup (like tea) for 20 minutes on an indirect heat at 80 °C.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hamedan Imam Khomeini Clinic

Full name of responsible person
Dr. Zohreh Kahramfar

Street address
Mirzadeh Eshghi Street, Hamedan Imam Khomeini Clinic, Hamedan Imam Khomeini Clinic

City
Hamedan

Province
Hamadan

Postal code
6517789971

Phone
+98 81 3825 2440

Fax
+98 81 3437 3606

Email
kahramfar@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Hamedan University of Medical Science

Full name of responsible person
Zohreh Kahramfar

Street address
Hamedan University of Medical Science, Shahid Fahmideh Street, Hamedan

City
Hamedan

Province
Hamadan

Postal code
6517838678

Phone
+98 81 3825 2440

Fax
+98 81 3825 2440

Email
kahramfar@umsha.ac.ir

Web page address

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, Hamedan University of Medical Science

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Hamedan Agricultural and Natural Resources Research and Education Center

Full name of responsible person
Mohsen Rajabi

Position
University Teacher, Researcher

Latest degree
Master

Other areas of specialty/work
Biotechnology

Street address
5 Km of Tehran Road, Hamedan Agricultural and Natural Resources Research and Education Center

City
Hamedan

Province
Hamadan

Postal code
6519631169

Phone
+98 81 3437 3587

Fax
+98 81 3437 3606

Email
m.rajabi@iauh.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan Agricultural and Natural Resources Research and Education Center

Full name of responsible person
Ramezan Kalvandi

Position

PhD Degree, Faculty Member

Latest degree
Ph.D.

Other areas of specialty/work
Medicinal plants

Street address
5 Km of Tehran Road, Hamedan Agricultural and Natural Resources Research and Education Center

City
hamedan

Province
Hamadan

Postal code
6519631169

Phone
+98 81 3437 3587

Fax
+98 81 3437 3606

Email
rkalvendi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hamedan Agricultural and Natural Resources Research and Education Center

Full name of responsible person
Mohsen Rajabi

Position
University Teacher, Researcher

Latest degree
Master

Other areas of specialty/work
Biotechnology

Street address
5 Km of Tehran Road, Hamedan Agricultural and Natural Resources Research and Education Center

City
hamedan

Province
Hamadan

Postal code
6519631169

Phone
+98 81 3437 3587

Fax
+98 81 3437 3606

Email
m.rajabi@iauh.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable