

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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

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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

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Hamedan University of Medical Science, Shahid Fahmideh Street, Hamedan

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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

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Person responsible for scientific inquiries

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Full name of responsible person

Ramezan Kalvandi

Position

PhD Degree, Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Medicinal plants

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Mohsen Rajabi

Position

University Teacher, Researcher

Latest degree

Master

Other areas of specialty/work

Biotechnology

Street 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