

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of Artichoke Leaf Extract on Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST) in the patients with Non Alcoholic Steatohepatitis (NASH).

Protocol summary

Summary

This study is parallel groups randomized clinical trial with a pre and post test design. The purpose of this study was to investigate the effects of Artichoke Leaf Extract on Alanine aminotransferase (ALT) and Aspartate aminotransferase (AST) in the patients with Non Alcoholic Steatohepatitis (NASH). NASH patients were recruited from Gastroenterology and hepatology clinic of Shahid Dr. Chamran hospital in Tehran, Iran in regard to inclusion and Exclusion criteria. To be included patients needed to have: (1) Abnormal serum transaminases ≥ 30 U/L (2) Fatty liver in ultrasonography. With these criteria 60 subjects considered in this study. Consent obtained from each patient. They could quit the study freely. The subjects were randomly assigned in two groups; intervention and placebo groups. Intervention group received 6 Cynarckol tablets daily after each meal (2 tablets after break fast, 2 tablets after lunch and 2 tablets after dinner) containing 2700 mg Artichoke Leaf Extract for 8 weeks and placebo group received 2700 mg placebo daily in 6 placebo tablets (2 tablets after break fast, 2 tablets after lunch and 2 tablets after dinner) for 8 weeks. Both groups receive diet and physical activity advice during the study. Diet, exercise and medical dosage were held constant throughout the study. In both groups Alanine aminotransferase (ALT), Aspartate aminotransferase (AST), Fasting blood glucose, Total Cholesterol, LDL Cholesterol, HDL Cholesterol, triglyceride levels were measured at the baseline and will measure at the end of intervention. The results will be compared in two groups by statistical analyses.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070218321N1**

Registration date: **2014-08-04, 1393/05/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-04, 1393/05/13

Registrant information

Name

Vajiheh Rangboo

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 28 3333 6001

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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences, Faculty of Health

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-06-22, 1393/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Artichoke Leaf Extract on Alanine aminotransferase (ALT) and Aspartate aminotransferase

(AST) in the patients with Non Alcoholic Steatohepatitis (NASH).

Public title

The effect of Artichoke Leaf Extract in the patients with Non Alcoholic Steatohepatitis (NASH).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Abnormal serum transaminases \geq 30 U/L ; Fatty liver in ultrasonography; At least one of the following, FBS greater than 100 mg/dL or a previous diagnosis of type II diabetes,obesity (Body mass index of 30 or higher),Blood pressure greater than 130/85 ,Triglyceride-levels greater than 150 mg/dl ,HDL-cholesterol lower than 40 mg/dl (men) and 50 mg/dl (women) ,Total cholesterol greater than 200 mg/dl. Exclusion criteria:Daily alcohol consumption;Type I diabetes;Concomitant liver diseases,Presence of HCV antibody or HBs antigen, auto-immune hepatitis, hemochromatosis, Wilson's disease, alpha1 anti-trypsin deficiency, Biliary obstruction;Use of livergol,Vit E, Vit C,UDCA,Heptotoxic Drug;Treatment with a drug known to induce NASH (amiodarone,calcium channel blocker, tamoxifen), and oral anticoagulation;Decompensated cirrhosis;Serious disease limiting life expectancy;Pregnancy and lactation;people who are Allergy sensitive to the Asteraceae/Compositae family.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences

Street address

Qazvin,Bahonar bolvar, Pardis, Qazvin University of Medical Sciences

City

qazvin

Postal code

59811-34197

Approval date

2013-10-09, 1392/07/17

Ethics committee reference number

28/20/7929

Health conditions studied

1

Description of health condition studied

non alcoholic steatohepatitis

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

alanine aminotransferase (ALT)

Timepoint

before and after intervention

Method of measurement

IU/Lit

2

Description

aspartate aminotransferas (AST)

Timepoint

before and after intervention

Method of measurement

IU/Lit

Secondary outcomes

1

Description

total cholestrol

Timepoint

before and after the intervention

Method of measurement

Mg/dL

2

Description

LDL-C

Timepoint

before and after the intervention

Method of measurement

Mg/dL

3

Description

HDL-C

Timepoint

before and after the intervention

Method of measurement

Mg/dL

4

Description

Triglycerid

Timepoint

before and after the intervention

Method of measurement

Mg/dL

5

Description

fasting blood sugar

Timepoint

before and after the intervention

Method of measurement

Mg/dL

Intervention groups

1

Description

placebo group received 6 placebo tablets daily (2 tablets after break fast ,2 tablets after lunch and 2 tablets after dinner) for 8 weeks.

Category

Placebo

2

Description

Intervention group received 6 Cynarckol tablets daily, containing 2700 mg Artichoke Leaf Extract after each meal (2 tablets after break fast ,2 tablets after lunch and 2 tablets after dinner) for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Chamran Hospital

Full name of responsible person

Dr. Seyed Amir Mansoor Rezadoost

Street address

Chamran Hospital, Sanaye street, Langari street, Nobonyad squire, Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Qazvin University of Medical Sciences, Faculty of Health

Full name of responsible person

Dr. Ali Safari Variani

Street address

Faculty of Health, Qazvin University of Medical Sciences, Pardis, Bahonar bolvar, Qazvin.

City

Qazvin

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Qazvin University of Medical Sciences, Faculty of Health

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**

Qazvin University of Medical Sciences

Full name of responsible person

Vajiheh Rangboo

Position

MS student in Nutrition

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mostafa Noroozi

Position

PHD of Nutrition, Assistant Professor of Nutrition
Department

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00

Fax**Email****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

Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Vajiheh Rangboo

Position