Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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 paralled 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 Gastroenterogy 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 grups ; 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 aminotrans (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 compare 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)

Phone

+98 28 3333 6001

Email address

vrangboo@qums.ac.ir

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 ≥ 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 squre,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
Qazvin University of Medical Sciences, Pardis, Bahonar bolvar, Qazvin.
City
Qazvin
Postal code
59811-34197
Phone
+98 28 3336 9581
Fax
Email
vrangboo@qums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr.Mostafa Noroozi
Position
PHD of Nutrition, Assistant Professor of Nutrition Department
Other areas of specialty/work
Street address
Qazvin University of Medical Sciences, Pardis, Bahonar bolvar, Qazvin
City
Qazvin
Postal code
59811-34197
Phone
+98 28 3333 5901
Fax
Email
mnoroozi@qums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Vajiheh Rangboo
Position
MS Student of Nutrition
Other areas of specialty/work
Street address
Qazvin University of Medical Sciences, Pardis, Bahonar bolvar, Qazvin
City
Qazvin
Postal code
Phone
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