Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

The effect of Chlorella Volgaris versus Arthichoke on patients with NAFLD- A randomized clinical trial

Protocol summary

Summary

Effects of Chlorella Vulgaris extract and Arthichoke on patients with Non-Alcoholic Fatty liver disease (NAFLD).This study has done by non blinded methods of clinical trial. Inclusion criteria and methods: 90 patients were enrolled by NAFLD(has been diagnosed with liver ultrasound and increased alanine aminotransferase (ALT) less than 5 times the normal) and without other secondary liver disease, body mass index between(25-35), then patients were randomly divided into three groups. Intervention:30 patient as the control group only received treatment with metformin and vitamin E,the second group,30 patients were treated with Chlorella supplements and third group (30 patients), were treated with Arthichoke supplements.Patients are recommended to have daily 20 minutes of physical activity and diet 500 kcal less than the previous in a group that have BMI 30-35 and 300 kcal in BMI 25-30 as well as. Main outcom: After eight weeks of treatment is measured serum levels of liver enzymes (ALT) and its level is considered as a measure of treatment response. (Reduced serum levels of at least 3 times as the response to treatment).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101619554N1**
Registration date: **2015-04-02, 1394/01/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-04-02, 1394/01/13

Registrant information

Name

Maryam Jameshorani

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research,Zanjan University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Chlorella Volgaris versus Arthichoke on patients with NAFLD- A randomized clinical trial

Public title

The effect of Chlorella Volgaris versus Arthichoke on patients with NAFLD- A randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Inclusion criteria: Proven fatty liver by Ultrasound, Increase liver enzyme alanine aminotransferase (ALT) between 1.5 to 5 times the normal; The mean BMI between 25-35 Exclusion criteria:

Patients with nonalcoholic steatohepatitis; Patients with systemic diseases such as diabetes - and other inflammatory diseases; Positive serology for hepatitis viral, anti-mitochondrial antibody (AMA); positive anti-nuclear antibody (ANA); TIBC increased serum iron and transferrin,TIBC, positive serum ceruloplasmin; Other secondary causes of fatty liver, Transferrin saturation more than 45.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **200**

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
-

Secondary trial Id
-

Registration date
empty

2

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee Zanjan University of Medical Sciences

Street address
Zanjan University of Medical Sciences,Republic Street, Freedom Boulevard , opposit of Saderat Bank, Zanjan University of Medical Sciences

City
Zanjan

Postal code

Approval date
2011-09-23, 1390/07/01

Ethics committee reference number
01-63-03/91

Health conditions studied

1

Description of health condition studied
Fatty liver

ICD-10 code
K75.8

ICD-10 code description
nonalcoholic steatohepatitis

Primary outcomes

1

Description
Liver Function Test

Timepoint
2m after intervention

Method of measurement
Eliza method

Secondary outcomes

1

Description
BMI(Body Mass Index)

Timepoint
2m

Method of measurement
kg/m2.

2

Description
Blood Presser

Timepoint
2m

Method of measurement
Digital manometer

3

Description
Lipid Profil

Timepoint
2month

Method of measurement
Eliza

4

Description
Blood sugar
Timepoint
2month
Method of measurement
Eliza

Intervention groups

1

Description
Intervention:30 patient as the control group only received treatment with metformin and vitamin E, The second group,30 patients were treated with Chlorella supplements and third group (30 patients),were treated with Arthichoke supplements.Patients are recommended to have daily 20 minutes of physical activity and diet 500 kcal less than the previous in a group that have BMI 30-35 and 300 kcal in BMI 25-30 as well as. Main outcom:After eight weeks of treatment is measured serum levels of liver enzymes (ALT) and its level is considered as a measure of treatment response. (Reduced serum levels of at least 3 times as the response to treatment).
Category
Treatment - Drugs

2

Description
In the control group, 30 patients receiving metformin 500 mg(is made of Eksir company) 2 times a day, after breakfast and dinner,also vitamin E 400 IU (is made of Eksir company)once a day after lunch.Nutrition and exercise advice given to patients for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital Clinic
Full name of responsible person
Maryam Jameshorani
Street address
Valiasr Hospital , Keshavarz Street,Higher than the Asr Square,Highway Sheikh Fadlallah Noori,Zanjan
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research,Zanjan University of Medical Sciences
Full name of responsible person
Dr Faghihzade Soghrat
Street address
Vice Chancellor for Research,Zanjan University of Medical Sciences;Jomhori Street ; front of Saderat Bank
City
Zanjan
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,Zanjan 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
Zanjan University of Medical Sciences,
Full name of responsible person
Vice Chancellor for Research,Zanjan University of Medical Sciences,.Dr Faghihzade Soghrat
Position
Statistician
Other areas of specialty/work
Street address
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Person responsible for scientific inquiries

Contact
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Full name of responsible person

Maryam Jameshorani

Position

Internist

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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