

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 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 been 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 patients 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 outcome: 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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dr.shirinjameshorani@zumc.ac.ir

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: 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, opposite 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

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Internist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Jameshorani

Position

Internist

Other areas of specialty/work

Street 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