

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effects of Cichorium intybus seed on treatment of nonalcoholic fatty liver disease, a randomized double-blind clinical trial

Protocol summary

Summary

(1) Objectives : The aim of this study is to analyse effects of Cichorium intybus seed on liver enzyme, body composition and sonographic findings in patients with Non-Alcoholic Fatty Liver Disease. (2) Design: randomized, double blind trial study. (3) Setting and conduct: 60 patients suffering from fatty liver disease will be selected among patients referring to Endocrinology and Metabolism Research Center in Zanjan , and will be assigned into intervention and control group. (4) Participants: inclusion criteria: sign the consent form: age between 20-45 years: BMI between 25-35: Ultrasound evidence confirm fatty liver disease: ALT level: more than 60 for men and 38 for women: negative pregnancy test: No breastfeeding: No alcohol consumption: non diabetes , kidney disease (Cr more than 1.5), hypothyroidism, hyperthyroidism, acute and chronic liver diseases, malignancy: non hepatotoxic drug consumption since 6 months ago: no allergy to Cichorium intybus. Exclusion Criteria: positive pregnancy test: allergy to Cichorium intybus: no tendency to continue the program. (5) Intervention: Consumption of Cichorium intybus seed syrup, 8 cc bid and in control group Consumption of 8 cc bid placebo for one month (6) main outcome measures: at the beginning and end of the study, blood levels of alanin aminotransferase and aspartat aminotransferase, FBS, LDL, HDL, body composition and ultrasonography will be taken.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016061228411N1**

Registration date: **2017-05-31, 1396/03/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-31, 1396/03/10

Registrant information

Name

Maral Marzban

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3342 4771

Email address

maralmarzban@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Vice chancellor of Zanjan University of Medical Science

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Cichorium intybus seed on treatment of nonalcoholic fatty liver disease, a randomized double-blind clinical trial

Public title

Effect of Cichorium Intybus seed on treatment of nonalcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: sign the consent form! age between 20-45 years! BMI between 25-35!Ultrasound evidence confirm fatty liver disease! ALT level: more than 60 for men and 38 for women! negative pregnancy test! No breastfeeding! No alcohol consumption! non diabetes , kidney disease(Cr more than 1.5), hypothyroidism, hyperthyroidism, acute and chronic liver diseases, malignancy! non hepatotoxic drug consumption since 6 months ago! no allergy to Cichorium intybus. Exclusion Criteria: positive pregnancy test! allergy to Cichorium intybus! no tendency to continue the program.

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

2

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

Ethical Committee of zanjan medical university

Street address

Zanjan University of Medical Sciences- Azadi square-
Zanjan

City

Zanjan

Postal code

00982433567401

Approval date

2016-11-05, 1395/08/15

Ethics committee reference number

195.ZUMS.REC.1395

Health conditions studied

1

Description of health condition studied

non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

ALT

Timepoint

before intervention, 1 and 2 months after intervention

Method of measurement

photometric

2

Description

AST

Timepoint

before intervention, 1 and 2 months after intervention

Method of measurement

photometric

3

Description

FBS

Timepoint

before intervention, 1 and 2 months after intervention

Method of measurement

Fasting blood glucose concentrations

4

Description

Triglisirid

Timepoint

before intervention, 1 and 2 months after intervention

Method of measurement

blood test

5

Description

Cholestrol

Timepoint

before intervention, 1 and 2 months after intervention

Method of measurement

blood test

6

Description

LDL

Timepoint

before intervention, 1 and 2 months after intervention

Method of measurement

blood test

7

Description

HDL

Timepoint

before intervention, 1 and 2 months after intervention

Method of measurement

blood test

8

Description

BMI

Timepoint

before intervention, 1 and 2 months after intervention

Method of measurement

weight with kilograms on a scale,height with meters with the use of a rubber meter

9

Description

The severity of fatty liver

Timepoint

before intervention, 1 and 2 months after intervention

Method of measurement

ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cichorium intybus seed syrup,8cc bid

Category

Treatment - Drugs

2

Description

Control group: standardized placebo 8 cc bid

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Special clinic in Zanzan University of Medical Sciences

Full name of responsible person

Maral Marzban

Street address

7 Tir st, Zanzan

City

Zanzan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice chancellor of Zanzan University of Medical Science

Full name of responsible person

Dr. Soghrat Faghihzadeh

Street address

Headquarter of medical science,deputy research & technology, Jomhori street, Azadi sq, Zanzan

City

Zanzan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Vice chancellor of Zanzan University of Medical Science

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

Zanzan University of Medical Sciences

Full name of responsible person

Maral Marzban

Position

PhD student of traditional medicine

Other areas of specialty/work

Street address

Valiasr medical education center , after Valiasr sq, Zanzan Zanzan Zanzan Iran, Islamic Republic Of

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr.Maryam Jameshorani

Position

Internist

Other areas of specialty/work

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Person responsible for updating data

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PhD student of traditional medicine

Other areas of specialty/work

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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