Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 aminotranspherase and aspartat aminotranspherase, 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
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Iran (Islamic Republic of)
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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 Zanjan University of Medical Sciences
Full name of responsible person
Maral Marzban
Street address
7 Tir st, Zanjan
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Vice chancellor of Zanjan 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, Zanjan
City
Zanjan
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 Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Maral Marzban
Position
PhD student of traditional medicine
Other areas of specialty/work
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Valiasr medical education center , after Valiasr sq, Zanjan Zanjan Zanjan 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

Contact

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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