

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Effect of the Root Extract of Cichorium Intybus Formula on Reducing Alanine Aminotransferase (ALT) in Non-alcoholic Fatty Liver Disease: A Randomized Double-blind Clinical Trial Including Placebo

Protocol summary

Summary

The study investigates effect of the extract of Cichorium intybus root in reducing the alanine aminotransferase level and compares it with the placebo in patients with non-alcoholic fatty liver disease. This study is a randomized double-blind clinical trial. A number of 60 people were selected for the study. Inclusion Criteria: age from 18 to 70 years; fatty liver disease grade 1, 2 or 3 diagnosed by ultrasound; No current use of another drug for fatty liver treatment which has not been taken before. Exclusion Criteria: Advanced cardiovascular disease, pulmonary or renal disease; Pregnancy; Breast feeding; Allergy to Cichorium intybus; Non-compliance with medication; Psychiatric diseases complicating the results evaluation or causing patient's lack of cooperation; Advanced cirrhosis , Hepatitis and other liver diseases except non-alcoholic fatty liver; alcohol consumption by patients; Fatty acid oxidation disorder (congenital);Patients with diabetes who are treated with insulin. The duration of intervention is two months, where in the Intervention 1 Cichorium intybus root extract, and in the Intervention 2 corn starch. Duration of intervention: 2 months case 1: chicory root case 2: corn starch Before and after taking the drug, Alanine aminotransferase ,Fasting blood sugar, Total cholesterol,Triglycerides,High-density lipoprotein, Low-density lipoprotein, Platelets, Albumine, Impaired glucose tolerance,Aaspartat aminotransferase, platelets, albumin are measured by an accredited laboratory. The patients' body mass indexes before and after taking the drug are calculated. If the evaluation confirms positive results, the extract of Cichorium intybus root can be used for the treatment of patients with non-alcoholic fatty liver disease. e aminotransferase level and compares it with the placebo in patients with non-alcoholic fatty liver disease. This study is a randomized double-blind clinical

trial. A number of 60 people were selected for the study. Inclusion Criteria: age from 18 to 70 years; fatty liver disease grade 1, 2 or 3 diagnosed by ultrasound; No current use of another drug for fatty liver treatment which has not been taken before.Exclusion Criteria: Advanced Heart - cardiovascular, pulmonary or renal disease; Pregnancy; Breast feeding; Allergy to Cichorium intybus; Non-compliance with medication; Psychiatric diseases complicating the results evaluation or causing patient's lack of cooperation; Advanced cirrhosis , Hepatitis and other liver diseases except non-alcoholic fatty liver;Aalcohol consumption by patients; Fatty acid oxidation disorder (congenital);Patients with diabetes who are treated with insulin. The duration of intervention is two months, where in the Intervention 1 Cichorium intybus root extract, and in the Intervention 2 corn starch. Duration of intervention: 2 months case 1: chicory root case 2: corn starch Before and after taking the drug, Alanine aminotransferase ,Fasting blood sugar, Total cholesterol,Triglycerides,High-density lipoprotein,Low-density lipoprotein, Platelets,Albumine, Impaired glucose tolerance,Aaspartat aminotransferase, platelets, albuminare are measured by an accredited laboratory. The patients' body mass indexes before and after taking the drug are calculated. If the evaluation confirms positive results, the extract of Cichorium intybus root can be used for the treatment of patients with non-alcoholic fatty liver disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121615825N1**

Registration date: **2014-06-09, 1393/03/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-09, 1393/03/19

Registrant information**Name**

Maryam Nikkhajooei

Name of organization / entity

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center Shahid Behes

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the Root Extract of Cichorium Intybus Formula on Reducing Alanine Aminotransferase (ALT) in Non-alcoholic Fatty Liver Disease: A Randomized Double-blind Clinical Trial Including Placebo

Public title

Effect of the Root Extract of Cichorium Intybus Formula on Fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion / Exclusion : Inclusion Criteria: Patient age of 18 to 70 years; fatty liver disease grade 1, 2 or 3 diagnosed by ultrasound; No current use of another drug for fatty liver treatment which has not been taken before.

Exclusion Criteria :Advanced cardiovascular diseases, pulmonary or renal diseases; Pregnancy; Breast feeding; Allergy to Cichorium intybus; Non-compliance with medication; Psychiatric diseases complicating the results evaluation or causing patient's lack of cooperation; Advanced cirrhosis; Hepatitis and other liver diseases except non-alcoholic fatty liver; alcohol consumption by patients; Fatty acid oxidation disorder (congenital); Patients with diabetes who are treated with insulin.

Age

From **18 years** old to **70 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**

Medical Ethics Committee, Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Velenjak St., Shahid Chamran Highway university of Medical Sciences.

City

Tehran

Postal code**Approval date**

2013-12-04, 1392/09/13

Ethics committee reference number

1392-1-1-163-1173, 143

Health conditions studied**1****Description of health condition studied**

Fatty liver disease

ICD-10 code

k70-k77

ICD-10 code description

Diseases of liver

Primary outcomes**1****Description**

Alanine Aminotransferase

Timepoint

Before intervention and two months after intervention

Method of measurement

Spectrophotometer

Secondary outcomes

1

Description

Aspartat Aminotransferase

Timepoint

Before intervention and two months after intervention

Method of measurement

Spectrophotometer

2

Description

Fasting blood sugar

Timepoint

Before intervention and two months after intervention

Method of measurement

Spectrophotometer

3

Description

Total Cholesterol

Timepoint

Before intervention and two months after intervention

Method of measurement

Spectrophotometer

4

Description

Triglycerides

Timepoint

Before intervention and two months after intervention

Method of measurement

Spectrophotometer

5

Description

High-density lipoprotein

Timepoint

Before intervention and two months after intervention

Method of measurement

Spectrophotometer

6

Description

Low-density lipoprotein

Timepoint

Before intervention and two months after intervention

Method of measurement

Spectrophotometer

7

Description

Platelets

Timepoint

Before intervention and two months after intervention

Method of measurement

Spectrophotometer

8

Description

Albumin

Timepoint

Before intervention and two months after intervention

Method of measurement

Spectrophotometer

9

Description

Glucose tolerance test

Timepoint

Before intervention and two months after intervention

Method of measurement

Spectrophotometer

10

Description

Body Mass Index

Timepoint

Before intervention and two months after intervention

Method of measurement

Scale and Meter

Intervention groups

1

Description

Intervention 1: A capsule containing 500 mg of Cichorium intybus root extract is given to the patients group in the morning before breakfast.

Category

Treatment - Drugs

2

Description

Intervention 2: Two capsules containing corn starch are given to the control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Behesh

Full name of responsible person

Maryam Nikkhajoei

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center Shahid Behes

Full name of responsible person

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Street address

No.8 Shams Alley, Across Tavanir St., Vali Asr Street

City

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center Shahid Behes

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**

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center Shahid Behes

Full name of responsible person

Maryam Nikkhajooei

Position

Ph.D student of Traditional Medicine

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Person responsible for scientific inquiries

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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