Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 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 alaninThe 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 cholestrol,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 suger, Total cholestrol,Triglycerides,High-density lipoprotein,Low-density lipoprotein, Platelets,Albumine, Imaired 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
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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
Aaspartat 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 Nikkhajooei
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Sponsors / Funding sources

1

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

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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