

# 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, Aspartate 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; 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, Aspartate 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.

#### 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)

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+98 88773522

**Email address**

mnik@sbmu.ac.ir

**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**

Maryam Nikkhajooei

**Street address**

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

**City**

Tehran

**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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Position**

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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*