

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effects of Hydroalcoholic extract of Cichorium intybus leaves on liver functional indexes in patient with Non Alcoholic Fatty liver disease

Protocol summary

Study aim

Effect of hydroalcoholic extract of Cichorium intybus leaves on liver functional indexes in patient with non alcoholic fatty liver disease

Design

This clinical trial was performed on 40 patients, divided into two groups of 20, including a control group and parallel groups. This study is blinded and simple randomization is used.

Settings and conduct

The field of work is clinical - internal. This study is performed in the gastrointestinal clinic of Tohid Hospital in Sanandaj. The intervention group is given a 500 mg capsule of Cichorium intybus leaves daily for two months, along with standard treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: subjects over 20 years old who were diagnosed with non alcoholic fatty liver disease (NAFLD) by Sonography and increased levels of ALT and AST
Exclusion criteria: Alcohol consumption of more than 140cc in men and 70 cc in women per week, Patients with viral hepatitis, diabetes, Patients taking lipid-lowering drugs, Pregnancy and Lactation, Patients taking drugs affecting liver enzymes, Patients with autoimmune diseases, History of bleeding and hemostatic disorders, Patients taking anticoagulants like warfarin, Patients with allergies to herbs and herbal medicines

Intervention groups

Intervention group: Cichorium intybus, oral capsule, 500 mg, Once a day for two months with standard treatment
Control group: placebo containing starch, oral capsule, 500 mg, Once a day for two months with standard treatment

Main outcome variables

Alanine Aminotransferase (ALT); Aspartate Aminotransferase (AST); Alkaline Phosphatase (ALP); Bilirubin; Cholesterol; Triglyceride; High Density Lipoprotein (HDL); Low Density Lipoprotein (LDL); Grade of fatty liver; Body Mass Index (BMI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190415043279N2**

Registration date: **2020-01-02, 1398/10/12**

Registration timing: **prospective**

Last update: **2020-01-02, 1398/10/12**

Update count: **0**

Registration date

2020-01-02, 1398/10/12

Registrant information

Name

Pezhman Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3324 9435

Email address

p.sharifi@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-05, 1398/10/15

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Hydroalcoholic extract of Cichorium intybus leaves on liver functional indexes in patient with Non Alcoholic Fatty liver disease

Public title

The effect of Cichorium intybus on non alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with aminotransferases greater than 1.5 times the normal maximum Ultrasound images with Stage 2, 3

Exclusion criteria:

Alcohol consumption (more than 140 cc in men and 70 cc in women per week) Patients with viral hepatitis Diabetic patients Patients taking lipid-lowering drugs Pregnancy and lactation Patients taking drugs that affect the liver enzymes Patients with autoimmune diseases People with a history of bleeding and hemostatic disorders Patients taking anticoagulants like warfarin Patients with allergies to herbs and herbal remedies

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block randomization method with a block size of 4. Sampling method at this study will be according to random allocation. Participants will enter the study according to inclusion criteria, and then will be divided into two groups according to randomization table. One group will receive chicory (Capsule containing Cichorium intybus) and the other will receive placebo. The participants and administrator do not have any information about content of capsules (double blinded study). The list of randomization was computer-generated. supplements and placebo capsules were placed in completely identical packages and were coded by someone who was unaware of the nature of the study in numbered bottles based on the list. And another person who was unaware of the contents of the pack provided them to the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

All supplements and placebo capsules were identical with respect to appearance and only differed in coding of the capsules. The treatment code of the intervention supplements was blinded for subjects, investigators and staff involved in the conduct of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2019-04-29, 1398/02/09

Ethics committee reference number

IR.MUK.REC.1398.013

Health conditions studied

1

Description of health condition studied

Non Alcoholic Fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Alanine Aminotransferase (ALT)

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

2

Description

Aspartate Aminotransferase (AST)

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

3

Description

Grade of fatty liver

Timepoint

At baseline and end of the study

Method of measurement

Sonography

4

Description

Alkaline Phosphatase (ALP)

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

5

Description

Bilirubin

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

6

Description

Cholesterol

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

7

Description

Triglyceride

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

8

Description

High Density Lipoprotein (HDL)

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

9

Description

Low Density Lipoprotein (LDL)

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

10

Description

Fasting Blood Sugar (FBS)

Timepoint

At baseline and end of the study

Method of measurement

Using biochemical method and Pars azmoon Company's Kit

11

Description

Body Mass Index (BMI)

Timepoint

At baseline and end of the study

Method of measurement

by measuring height and weight using a scale and height meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Capsule containing hydroalcoholic extract of Cichorium intybus leaves at a dose of 500 mg per day for two consecutive months. These oral capsules of Cichorium intybus leaves are prepared by a reputable pharmacist.

Category

Placebo

2

Description

Control group: Placebo in capsules at a dose of 500 mg per day for two consecutive months. These placebo oral capsules contain starch and are prepared by a reputable pharmacist.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Clinic of Tohid Hospital

Full name of responsible person

Dr. Vahid Yousefinejad

Street address

Tohid Hospital, Geriashan Ave

City

Sanandaj

Province

Kurdistan

Postal code

6616812131

Phone

+98 87 3366 4645

Email

hooman56y@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr. Afshin Maleki

Street address

Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.

City

Sanandaj

Province

Kurdistan

Postal code

6617713466

Phone

+98 87 3366 4645

Email

maleki43@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Vahid Yousefinejad

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Forensic Medicine

Street address

Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

6617713466

Phone

+98 87 3366 4645

Email

hooman56y@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Vahid Yousefinejad

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Email

hooman56y@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Vahid Yousefinejad

Position

Assistant Professor

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Email

hooman56y@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable