Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

Study aim
Effect of hydroalcoholic extract of Cichorium intybus leaves on liver functional indexes in patient with non alcholic 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 alcholic 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; Cholestrol; 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 Alcholic Fatty liver disease

Public title
The effect of Cichorium intybus on non alcholic 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 Alcholic 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
Cholestrol
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 iral 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
Asisstant 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 updating data

Contact
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Vahid Yousefinejad
Position
Asisstant 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

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