Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

The effects of aqueous extract of Cichorium Intybus L on non-aloholic fatty liver disease

Protocol summary

Study aim

Determination of the Effect of Chicory Extract on Non-Alcoholic Fatty Liver

Design

In this study, 60 eligible non-alcoholic fatty liver participants who are referred to the Gastroenterology Clinic of Velayat Hospital, Qazvin are selected.The participants are then randomly assigned to intervention and control groups and each person is assigned a code and will receive an intervention (Chicory or placebo) based on the group.

Settings and conduct

This study was designed with the aim of helping to treatment patients with non-alcoholic fatty liver in a randomized, double-blind, placebo-controlled clinical trial. In this study, 60 patients with non-alcoholic fatty liver referred to the Gastroenterology Clinic of Velayat hospital, Qazvin province will study based on the criteria for entry. For all participants, a biochemical test (fasting blood glucose, total cholesterol, triglyceride, HDL, LDL, ALT, AST, alkaline phosphatase) will be performed in a specific laboratory at the beginning of the study. Meanwhile, liver and bile duct ultrasonography will be performed to determine the degree of fatty liver in a radiological center under the supervision of a specific radiologist. Anthropometric measurements including weight, height and waist circumference will be measured. Participants are then randomly assigned to either a case or control group, and will receive chicory capsules (case group) or placebo (control group) for 12 weeks. Biochemistry tests and other measurements will be repeated 6 weeks after the intervention and at the end of 12 weeks. The liver and bile duct ultrasonography will again performed at the end of 12 weeks. Finally, using statistical analysis, we will investigate the effect of chicory extract on non-alcoholic fatty liver disease.

Participants/Inclusion and exclusion criteria

Samples will be selected from people with non-alcoholic fatty liver disease of both genders and aged 18 to 65 years. If there are other causes of liver disease, pregnancy, lactation, malignancy, cardiovascular disease, diabetes, hypothyroidism, taking hepatotoxic drugs or drugs using for NAFLD management, the person will be excluded from the study.

Intervention groups

The study include 30 non-alcoholic fatty liver patients in the case group that will receive two 500 mg capsules of chicory extract per day, for 12 weeks. Also, 30 non-alcoholic fatty liver patients will be in the control group receiving 2 capsules of 500 mg per day for 12 weeks in the same way as the case group and containing starch as a placebo.

Main outcome variables

grade of fatty liver disease; serum aminotransferases levels; fasting plasma glucose ; lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171216037911N1**
Registration date: **2018-01-03, 1396/10/13**
Registration timing: **retrospective**

Last update: **2018-01-03, 1396/10/13**
Update count: **0**

Registration date

2018-01-03, 1396/10/13

Registrant information

Name

Mahsa Asar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3368 7126

Email address

mahsa_assar@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2016-12-20, 1395/09/30
Expected recruitment end date
2017-12-21, 1396/09/30
Actual recruitment start date
2016-12-20, 1395/09/30
Actual recruitment end date
2017-12-13, 1396/09/22
Trial completion date
empty

Scientific title
The effects of aqueous extract of Cichorium Intybus L on non-aloholic fatty liver disease

Public title
The effects of Cichorium fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
diagnosis of NAFLD according to ultra-sonography age between 18 to 65 years increase SGPT leve more than 30mgr/dl
Exclusion criteria:
Other causes of liver disease, including viral hepatitis or autoimmune, high alcohol consumption (more than 210 g / week in men and more than 140 g / week in women), Wilson's disease, hereditary hemochematosus, alpha1-antitrypsin deficiency and cirrhosis gestation and lactation; diagnosis of cancers consumption of hepatotoxic drugs or drugs using for management of NAFLD diagnosis of cardiovascular diseases diagnosis of diabetes mellitus diagnosis of hypothyroidism
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Actual sample size reached: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible participants in the study will randomly assign to two intervention and control groups. A randomized, stratified sampling method will use to control the confounding factors (age and gender) and the samples will first divide into two sex groups (male and female) and then will categorize again in each group based on age (less than 35 years and more than 35 years). Finally, the samples in each class will be randomly assigned to intervention or control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Each participant is randomly assigned a colored card (green for the case and blue for the control group). Participants are informed that they may be in either case and control group and finally, members of the control group will receive Chicory if they want it. Principle investigator does not know the meaning of colored cards.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Qazvin University of Medical Sciences
Street address
Qazvin University of Medical Sciences, Shahid Bahonar Blv, Qazvin, Iran
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2017-11-29, 1396/09/08
Ethics committee reference number
IR.QUMS.REC.1396.334

Health conditions studied

1

Description of health condition studied
nonalcoholic fatty liver disease
ICD-10 code
K76
ICD-10 code description
Other diseases of liver

Primary outcomes

1

Description
grade of fatty liver
Timepoint

before & 12 weeks after intervention

Method of measurement

liver and bile duct supersonic graphy

2

Description

Aspartate aminotransferases

Timepoint

before intervention, 6 weeks after beginning of the intervention, 12 weeks after beginning of the intervention

Method of measurement

blood sample

3

Description

waist circumfrence

Timepoint

before intervention, 6 weeks after beginning of the intervention, 12 weeks after beginning of the intervention

Method of measurement

by using of meter

Secondary outcomes

1

Description

serum Alanine Aminotransferase

Timepoint

before intervention, 6 weeks after beginning of the intervention, 12 weeks after beginning of the intervention

Method of measurement

blood sample

2

Description

serum ALP

Timepoint

before intervention, 6 weeks after beginning of the intervention, 12 weeks after beginning of the intervention

Method of measurement

blood sample

3

Description

weight

Timepoint

before intervention, 6 weeks after beginning of the intervention, 12 weeks after beginning of the intervention

Method of measurement

Mechanical scale

4

Description

serum triglyceride

Timepoint

before intervention, 6 weeks after beginning of the intervention, 12 weeks after beginning of the intervention

Method of measurement

blood sample

5

Description

Total cholestrol

Timepoint

before intervention, 6 weeks after beginning of the intervention, 12 weeks after beginning of the intervention

Method of measurement

blood sample

6

Description

serum HDL

Timepoint

before intervention, 6 weeks after beginning of the intervention, 12 weeks after beginning of the intervention

Method of measurement

blood sample

7

Description

serum LDL-C

Timepoint

before intervention, 6 weeks after beginning of the intervention, 12 weeks after beginning of the intervention

Method of measurement

blood sample

8

Description

fasting plasma glucose

Timepoint

before intervention, 6 weeks after beginning of the intervention, 12 weeks after beginning of the intervention

Method of measurement

blood sample

Intervention groups

1

Description

Intervention group: They will receive powder of aqueous extracts of 15 g chicory (equivalent to 1 g of extract) prepared by Avigeh Tejarat Sepehr Co. as two 500 mg

capsules daily, for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive daily 1 g of starch as placebo in the form of two 500 mg capsules similar to Chicory capsules for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Clinic of Velayat Hospital

Full name of responsible person

Mahsa Asar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Mahsa Asar

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Consultant

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Latest degree

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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

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

Analytic Code

Not applicable

Data Dictionary

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