Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The evaluation of the effect of brewed chicory leaf consumption on liver steatosis, enzymes, metabolic syndrome components, oxidative stress markers, C-reactive protein in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
The effect of brewed chicory leaf consumption on liver steatosis, enzymes, metabolic syndrome components, oxidative stress markers, C-reactive protein in patients with non-alcoholic fatty liver disease

Design
Clinical trial, control group, parallel groups, single blind, randomized with Stratified Block Randomization and sample size of 60 people, Phase 3 trial

Settings and conduct
The place of study is the Urmia Medical Clinic. Liver enzymes, lipid profile test, FBS, blood pressure, and possible side effects will be measured at baseline, week 6 and end of study and liver ultrasound, c-reactive protein, insulin, oxidative stress index (TAC, SOD) will be measured at the beginning and end of the study. Both groups will follow same diet.

Participants/Inclusion and exclusion criteria
Inclusion criteria included grade 2 and 3 non-alcoholic fatty liver disease, over 18 years, both sexes; Exclusion criteria included alcohol consumption, rheumatoid arthritis and other acute inflammatory diseases, NSAID, statins, phenytoin, karmabazepine, barbiturates, alpha-1 antitrypsin deficiency, heart failure, bone disease, Coeliac, vitamin, antioxidants, fiber and omega-3, anticoagulation and hepatotoxic drugs, hereditary hemochromatosis and Wilson's disease, renal disease, diabetes mellitus, hypothyroidism

Intervention groups
The intervention group will receive 15 grams of chicory leaf daily for 12 weeks, except for routine treatment by the gastroenterologist, and the control group will receive only the usual treatment.

Main outcome variables
ALT،AST،GGT،ALP، hs-CRP، Bilirubin total،SOD،TAC،CBC، Na, liver Steatosis, FBS, Alb, Ca, Creatinine, phosphorus, lipid profile, potassium

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190819044565N2**
Registration date: **2019-12-24, 1398/10/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-24, 1398/10/03**
Update count: **0**

Registration date
2019-12-24, 1398/10/03

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-23, 1398/08/01
Expected recruitment end date
2021-02-18, 1399/11/30
Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation of the effect of brewed chicory leaf consumption on liver steatosis, enzymes, metabolic syndrome components, oxidative stress markers, C-reactive protein in patients with non-alcoholic fatty liver disease

Public title
The evaluation of the effect of brewed chicory leaf consumption in patients with non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Grade 2 and 3 non-alcoholic fatty liver disease through observation of steatosis in ultrasound Older than 18 years Interested in attending in study that filled out an informed consent form
Exclusion criteria:
Mental, emotional, cognitive and mental disorders Grade 1 non-alcoholic fatty liver disease alcohol consumption Hepatitis B, Hepatitis C, Autoimmune Hepatitis, Liver Cancer, Cholestatic Liver Disease Rheumatoid arthritis and other acute inflammatory diseases Taking non-steroidal anti-inflammatory drugs, cholesterol-lowering drugs to control blood pressure such as statins, phenytoin, karmabazepine and barbiturates such as phenobarbital Alpha-1 antitrypsin deficiency Pancreatitis Heart failure Bone diseases Coeliac disease Supplement of Vitamin, Antioxidant, Fiber and Omega 3 Do not regularly use of brewed chicory leaf during the study Use of anticoagulants Hepatotoxic drugs Hereditary hemochromatosis Wilson's disease Pregnant women Lactating women Use of contraceptives drugs liver transplant kidney diseases Changes in the level of physical activity during the study Diabetes Mellitus Hypothyroidism
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using Stratified Block Randomization statistical software
Blinding (investigator's opinion)
Single blinded
Blinding description
The data analyzer will encode the names of the individuals and the clinical caregiver, researcher, outcome assessor, and data analyzer will be kept blind to the assigned study groups and the chicory leaf will be distributed by the person not present in the study
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
Department of Nutrition, Faculty of Medicine, Urmia University of Medical Sciences, Urmia, Iran
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Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2019-10-20, 1398/07/28
Ethics committee reference number
IR.UMSU.REC.1398.282

Health conditions studied

1

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

Primary outcomes

1

Description
Hepatic steatosis
Timepoint
Beginning and end of study (after 12 weeks)
Method of measurement
ultrasound

2

Description
Alanine transaminase
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

3

Description
Aspartate transaminase
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

4

Description
Gamma-glutamyl transferase
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

5

Description
alkaline phosphatase
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

6

Description
High-density lipoprotein
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

7

Description
Low-density lipoprotein
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

8

Description
Triglyceride
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

9

Description
Cholesterol
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

10

Description
FBS
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

11

Description
total antioxidant capacity
Timepoint
Beginning and end of study (after 12 weeks)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

12

Description
Superoxide dismutase
Timepoint
Beginning and end of study (after 12 weeks)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

13

Description
hs-CRP
Timepoint
Beginning and end of study (after 12 weeks)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

Secondary outcomes

1

Description
Insulin
Timepoint
Beginning and End of Study (Week 12)
Method of measurement
ELISA method, BT1500 machine

2

Description
HOMA-IR
Timepoint
Beginning and End of Study (Week 12)
Method of measurement

Formula

3

Description
QUICKI
Timepoint
Beginning and End of Study (Week 12)
Method of measurement
Formula

4

Description
Albumin
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

5

Description
Creatinine
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

6

Description
Bilirubin total
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

7

Description
CBC
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Using the cell counter

8

Description
Calcium
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

9

Description
Phosphorus
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
Enzymatic method with autoanalysis, BT1500 machine

10

Description
Sodium
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
blood sample

11

Description
potassium
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
blood sample

12

Description
Mean systolic and diastolic blood pressure
Timepoint
First, Sixth Week and End of Study (Week 12)
Method of measurement
blood pressure monitor

Intervention groups

1

Description
Intervention group: Apart from routine treatment by the gastroenterologist, they will receive 15 grams of chicory leaf daily for 12 weeks and And they will use dietary guidelines for Iranians to keep their diet uniform.
Category
Treatment - Other

2

Description
Control group: They will receive only routine gastrointestinal specialty treatment and will use dietary guidelines for Iranians to maintain a uniform diet.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tadbir clinic
Full name of responsible person
Mohammad Reza Mohammad Hossein Azar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
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Resalat Blvd.,Emergency Ave., Headquarters Urmia University of Medical Sciences, Deputy of Research and Building Technology, Urmia
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
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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

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

Data Dictionary

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