# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 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**
Samira Faraji

**Name of organization / entity**

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Iran (Islamic Republic of)

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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
**City**
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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Ammar, Urmia, West Azerbaijan Province
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Oroumia University of Medical Sciences
**Full name of responsible person**
Dr.Iraj Mohebbi
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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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FarajiSamira2019@yahoo.com
**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**
Samira Faraji
**Position**
Masters student
**Latest degree**
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**Other areas of specialty/work**
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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