Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Effect of dandelion capsule on improvement of liver fibrosis and liver function test among patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Effect of dandelion capsule on improvement of liver fibrosis and liver function test among patients with non-alcoholic fatty liver disease

Design
Randomized controlled trial, with two arm parallel group of 50 patients, will be enrolled between December 2018 and December 2019, and will follow for 3 months.

Settings and conduct
In this research, 50 eligible patients whit non-alcoholic fatty liver disease referring to Qom gastroenterology clinic were chosen. Then, patients by block randomization were randomly divided into two control and intervention groups. The intervention group will receive dandelion capsule and control group will receive placebo capsule. Participants does not know the intervention type

Participants/Inclusion and exclusion criteria
Inclusion criteria: grade 2 and 3 of Non-alcoholic fatty liver, hemoglobin above 13 in male and above 12 in female. Exclusion criteria: history of allergy to plants of asteraceae, diabetes and renal failure, pregnant and lactating women

Intervention groups
Intervention group: dandelion capsule, 300 mg, oral, twice a day, for 3 months. Control group: placebo capsule, oral, twice a day, for 3 months.

Main outcome variables
Liver stiffness change; change of liver enzymes levels in serum

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161205031252N10**
Registration date: **2018-11-22, 1397/09/01**
Registration timing: **registered_while_recruiting**
Last update: **2018-11-22, 1397/09/01**
Update count: **0**

Registration date
2018-11-22, 1397/09/01

Registrant information

Name
Ahmad Hormati

Name of organization / entity
Qom university of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 25 3612 2053

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hormatia@muq.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-22, 1397/09/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of dandelion capsule on improvement of liver fibrosis and liver function test among patients with non-alcoholic fatty liver disease

Public title
Effect of dandelion capsule on non-alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Grade 2 and 3 of Non-alcoholic fatty liver Hemoglobin above 13 in male and above 12 in female

Exclusion criteria:

History of allergy to plants of asteraceae Bile duct or intestinal obstruction Diabetes and renal failure Pregnant and lactating women Weight below 50 kg Consumers of lithium, tetracyclines, fluoroquinolones, blood glucose lowering drugs and blood thinners drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be assigned to two groups of intervention and control by block randomization. For this purpose blocks of size 4 will be used. Six blocks will include BAAB, ABBA, BABA, BBAA, ABAB, AABB. To hide the random allocation, the numbered dark envelopes will be used, in which the group name is specified in the random sequence generated. Then, according to the order of entering samples, for the first patient the envelope number one is opened and the group will be identified until the end.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and outcome assessor does not know the allocation

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qom University of Medical Sciences

Street address

No. 83, 4th alley, 1.1 alley, Safashahr Blvd

City

Qom

Province

Ghoum

Postal code

3716987366

Approval date

2018-11-06, 1397/08/15

Ethics committee reference number

IR.MUQ.REC.1397.128

Health conditions studied

1

Description of health condition studied

Nonalcoholic steatohepatitis

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

2

Description of health condition studied

Fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Liver stiffness

Timepoint

Three months after treatment

Method of measurement

Fibroscan

Secondary outcomes

1

Description

Blood levels of liver enzymes

Timepoint

Three months after treatment

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: Dandelion capsule, 300 mg, oral, twice a day, for 3 months

Category
Treatment - Drugs

2

Description
Control group: placebo capsule, oral, twice a day, for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hosbital
Full name of responsible person
Ahmad Hormati
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Hossein Saghafi
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Gastroenterology and Hepatology Disease Research Center, Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Squ
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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
Ghoum 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
Ghoum University of Medical Sciences
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Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is not a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available