

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 with 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)

Phone

+98 25 3612 2053

Email address

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

Ghoush

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

Street address

Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Square.

City

Qom

Province

Ghoum

Postal code

3719964797

Phone

+98 25 3612 2824

Email

hormatia@muq.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

Hossein Saghafi

Street address

Gastroenterology and Hepatology Disease Research Center, Shahid Beheshti Hospital, Shahid Beheshti Blvd, Azadegan Squ

City

Qom

Province

Ghoum

Postal code

3719964797

Phone

+98 25 3612 2824

Email

hormatia@muq.ac.ir

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

Full name of responsible person

Ahmad Hormati

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Gastroenterology and Hepatology Disease Research Center, Endoscopy Unit, Shahid Beheshti Hospital Qom, Shahid Beheshti Blv

City

Qom

Province

Ghoum

Postal code

3719964797

Phone

+98 256122053

Fax

+98 25 3612 2053

Email

Hormatia@muq.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ghoum University of Medical Sciences

Full name of responsible person

Ahmad Hormati

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Gastroenterology and Hepatology Disease Research Center, Endoscopy Unit, Shahid Beheshti Hospital

Qom, Shahid Beheshti Blv

City

Qom

Province

Ghousm

Postal code

3719964797

Phone

+98 25 3612 2053

Fax

+98 25 3612 2053

Email

Hormatia@muq.ac.ir

Web page address

City

Qom

Province

Ghousm

Postal code

3719964797

Phone

+98 256122053

Fax

+98 25 3612 2053

Email

Hormatia@muq.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ghousm University of Medical Sciences

Full name of responsible person

Ahmad Hormati

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Gastroenterology and Hepatology Disease Research Center, Endoscopy Unit, Shahid Beheshti Hospital Qom, Shahid Beheshti Blv

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