

# 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.

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**Email**

hormatia@muq.ac.ir

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

Ghous 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

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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**

Ghous 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**

Ghous 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

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Ghous University of Medical Sciences

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ghousm University of Medical Sciences

**Full name of responsible person**

Ahmad Hormati

**Position**

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**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