

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Evaluation of the effect of the compound extract of Cichorium intybus, Cynara scolymus and Silybum marianum on lipid accumulation in non-alcoholic fatty liver, in comparison with placebo in a randomized double-blind clinical trial

#### Protocol summary

##### Summary

The aim of this study is to investigate the effect of the compound extract of Cichorium intybus, Cynara scolymus and Silybum marianum on lipid accumulation in non-alcoholic fatty liver, in comparison with placebo in a randomized double-blind clinical trial. In this study the aquatic extract of Cichorium intybus, Cynara scolymus and Silybum marianum is prepared. Fifty patients are selected from those with diagnosed non-alcoholic fatty liver disease (NAFLD). Twenty five patients are randomly allocated to each group of treatment and placebo. Clinical characteristics and history is taken and gathered in questionnaire and data forms. Prior to intervention, liver sonography is performed to evaluate the lipid accumulation as the primary outcome. Liver function tests including liver enzyme activities, lipid profile including triglyceride, cholesterol, HDL, LDL and fasting blood glucose are measured as the secondary outcomes. In case of allergic response to the herbal medicine the patient is excluded from the study. Usage of common medications for the management of liver disease are not contraindicated and both groups are adjusted according to their drug usage so the major treatment will not be stopped. Informed consent will be obtained from all the participants. The herbal combination will be administered for two months, twice daily. Administration of the medicine and the placebo is concealed and both patients and the administrator will be blinded. Patients will be followed during the study and the compliance will be controlled. In case of the patient refusal to continue the treatment or the appearance of side effects the treatment will be stopped for that patient. After the intervention, liver sonography as well as lipid profile, fasting blood glucose and liver enzyme activities will be investigated again.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017042824198N2**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-11-19, 1396/08/28

##### Registrant information

##### Name

Mitra Nourbakhsh

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8670 3109

##### Email address

nourbakhsh.m@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator

##### Expected recruitment start date

2017-11-22, 1396/09/01

##### Expected recruitment end date

2018-02-23, 1396/12/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of the compound extract of Cichorium intybus, Cynara scolymus and Silybum marianum on lipid accumulation in non-alcoholic fatty liver, in comparison with placebo in a randomized double-blind clinical trial

**Public title**

Evaluation of the effect of the compound extract of chicory, globe artichoke and milk thistle on non-alcoholic fatty liver

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients who are willing to participate in the clinical trial; age range 20-70 years; diagnosed with nonalcoholic fatty liver disease; not affected with other disease states such as cardiovascular, digestive and endocrine disorders; not using other herbal medications at least 3 months prior to intervention.

Exclusion criteria: diagnosis of other disease states such as cardiovascular, digestive and endocrine disorders; taking herbal medications, showing allergic responses, unwillingness to participate

**Age**

From **20 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

randomization by table of random numbers

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

**Street address**

Hemmat Highway

**City**

Tehran

**Postal code**

1449614535

**Approval date**

2017-01-29, 1395/11/10

**Ethics committee reference number**

IR.IUMS.REC.1395.27413

**Health conditions studied****1****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**

level of lipid accumulation in liver

**Timepoint**

before intervention and 2 months after intervention

**Method of measurement**

sonography

**Secondary outcomes****1****Description**

liver enzyme assay

**Timepoint**

before intervention and after 2 months

**Method of measurement**

measurement in blood serum

**2****Description**

Fasting blood glucose

**Timepoint**

before intervention and after 2 months

**Method of measurement**

measurement in blood serum

**3****Description**

lipid profile

**Timepoint**

before intervention and after 2 months

**Method of measurement**

measurement in blood serum

## Intervention groups

### 1

#### Description

Intervention group 1: Compound extract of Cichorium intybus, Cynara scolymus and Silybum marianum; twice a day for two months

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2 (control): placebo which is similar to treatment but without herbal extract, twice a day for two months

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dr. Afrasiabian Clinic

##### Full name of responsible person

Dr. Hamidollah Afrasiabian

##### Street address

14, first floor, No.1839, North Kargar Ave.

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Investigator

##### Full name of responsible person

Dr. Hamidollah Afrasiabian

##### Street address

14, first floor, 1839, North Kargar Ave.

##### City

Tehran

#### Grant name

-

#### Grant code / Reference number

-

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Investigator

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Salamat Pouyan Novin Afra Pharmaceutical Company

##### Full name of responsible person

Dr. Hamidollah Afrasiabian

##### Position

Physician

##### Other areas of specialty/work

##### Street address

14, first floor, 1839, North Kargar Ave.

##### City

Tehran

##### Postal code

1413693115

##### Phone

+98 912 371 0023

##### Fax

##### Email

rezahododi.1367@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Mitra Nourbakhsh

##### Position

PhD

##### Other areas of specialty/work

##### Street address

Hemmat Highway

##### City

Tehran

##### Postal code

1449614535

##### Phone

+98 21 8670 3109

##### Fax

##### Email

nourbakhsh.m@iums.ac.ir

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. Mitra Nourbakhsh

##### Position

Faculty member

**Other areas of specialty/work**

**Street address**

Hemmat Highway

**City**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8670 3109

**Fax**

**Email**

**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*