Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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