Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effects of a Polyherbal compound on severity of steatosis and the levels of blood lipids and liver enzymes in patients with nonalcoholic fatty liver disease: A randomized controlled trial

Protocol summary

Study aim
on severity of steatosis and the levels of blood lipids and liver enzymes in patients with nonalcoholic fatty liver disease

Design
Sixty-four patients with NAFLD were randomly divided into treatment and control groups (2:1 ratio).

Settings and conduct
The subjects for the study were derived from the Clinic of Internal Medicine, Emam-Reza Hospital, Mashhad University of Medical Sciences. The liver ultrasound and biochemical markers including the serum lipids, liver enzymes, and glucose were evaluated before starting the study and at the end of the treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with nonalcoholic fatty liver disease with grade ≥ 2 of steatosis on sonography or grade 1 of steatosis + elevated serum alanine transaminase level

Intervention groups
Both control and group were advised to take healthy diet and exercise. The treatment group also received herbal capsules containing 400 mg of the mixture of Anethum graveolens, Citrus bigardia, Cynara scolymus, Portulaca oleracea, and Silybum marianum (2 capsules, thrice daily, for two months).

Main outcome variables
The primary outcome measures included change in grade of NAFLD in sonography and change in serum ALT level.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT2015123025772N1**
Registration date: **2016-04-08, 1395/01/20**
Registration timing: **prospective**

Last update: **2020-08-17, 1399/05/27**
Update count: **2**

Registration date
2016-04-08, 1395/01/20

Registrant information

Name
Seyyed Abbas Zojaji

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3711 2717

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Recruitment status
Recruitment complete

Funding source
Mashhad university of medical science, Exir teb zakaria company

Expected recruitment start date
2016-04-20, 1395/02/01

Expected recruitment end date
2016-06-15, 1395/03/26

Actual recruitment start date
2016-04-20, 1395/02/01

Actual recruitment end date
2019-02-20, 1397/12/01

Trial completion date
2019-03-19, 1397/12/28

Scientific title
Evaluation of the effects of a Polyherbal compound on severity of steatosis and the levels of blood lipids and

liver enzymes in patients with nonalcoholic fatty liver disease: A randomized controlled trial

Public title
Evaluation of the effect of a herbal mixture on non alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients with nonalcoholic fatty liver disease with grade ≥ 2 of steatosis on sonography or grade 1 of steatosis + elevated serum alanine transaminase level
Exclusion criteria:
Having special or chronic disease like auto immune diseases, hypothyroidism, lupus, renal dysfunction, cancers, heart diseases, and severe infections Cirrhosis or Hepatitis B and C Pregnancy and lactation Unwillingness to continue treatment with herbal compound
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Science
Street address
Pharmacological Research Center of Medicinal Plants, Faculty of Medicine, Pardis campus, Azadi square, Mashhad City, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Approval date
2015-06-17, 1394/03/27
Ethics committee reference number
IR.MUMS.fm.REC.1394.114

Health conditions studied

1

Description of health condition studied
Non alcoholic fatty liver desease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Alanine transaminase (ALT)
Timepoint
Before intervention, two month after intervention
Method of measurement
Blood examination

2

Description
Steatosis of liver
Timepoint
Before intervention, two month after intervention
Method of measurement
Sonography

Secondary outcomes

1

Description
aspartate transaminase (AST)
Timepoint
Before starting study and 2 months after starting study
Method of measurement
Blood analysis (kit)

2

Description
fasting blood glucose
Timepoint
Before starting study and 2 months after starting study
Method of measurement
Blood analysis (kit)

3

Description
serum lipids
Timepoint
Before starting study and 2 months after starting study
Method of measurement
Blood analysis (kit) for total cholesterol and triglyceride

Intervention groups

1

Description
The treatment group received herbal capsules containing 400 mg of the mixture of Anethum graveolens, Citrus bigardia, Cynara scolymus, Portulaca oleracea, and Silybum marianum (2 capsules, thrice daily, for two months)> Both treatment and control group were advised to take healthy diet and exercise.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital Special Clinic
Full name of responsible person
Seyyed Abbas Zojaji
Street address
Emam Reza Hospital, Emam Reza Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research, Mashhad University of Medical Science
Full name of responsible person
Dr Mohsen Tafaghodi
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Vice chancellor for Research of Mashhad University of Medical Science, Ghoreyshi Building, Daneshgah Avenue
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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
Vice chancellor for Research, Mashhad University of Medical Science
Proportion provided by this source
70
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

2

Sponsor
Name of organization / entity
The Zojaj Darman Toos Pharmaceutical Company
Full name of responsible person
Seyed Abbas Zojaji
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Pharmaceutical Technology Incubator of Mashhad university of medical science, Buali square,Mashhad
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Email
info@zojaj.club
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The Zojaj Darman Toos Pharmaceutical Company
Proportion provided by this source
30
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Zojaj darman toos Pharmaceutical Company
Full name of responsible person
Seyyed Abbas Zojaji
Position
Managing Director
Latest degree
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable