

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 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

Email address

zojajia881@mums.ac.ir

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 disease

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

Street address

Vice chancellor for Research of Mashhad University of Medical Science, Ghoreyshi Building, Daneshgah Avenue

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ramresearch@mums.ac.ir

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

Street address

Pharmaceutical Technology Incubator of Mashhad university of medical science, Buali square, Mashhad

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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

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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

Mashhsad Medical School, Pharmacological Research
Center of Medicinal Plants

Full name of responsible person

Ahmad Ghorbani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Position

Associate Prof.

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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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