

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the efficacy of traditional medicine based on *Coriandrum sativum* in comparison with placebo on the ultrasound grade and serum level of liver enzymes in patients with non-alcoholic fatty liver

Protocol summary

Study aim

Determination of the efficacy of traditional drug based on *Coriandrum sativum* on the ultrasound grade and serum level of liver enzymes in patients with non-alcoholic fatty liver in patients referred to Besat Clinic in Kerman in 1399-1400

Design

Clinical trial with control group, with parallel groups, double blind, randomized, phase 3 on 80 patients. The quadruple block method was used for randomization.

Settings and conduct

This study is a randomized clinical trial in patients referred to Besat Clinic in Kerman with symptoms of metabolic syndrome. The patients are randomly divided into two groups of drugs and placebo based on the quadruple block method. Due to the similarity of the drug and placebo, patients do not know which group they are in. On the other hand, drug and placebo coding is done by the pharmacist and the researcher is unaware of how patients are assigned to the groups until the end of the study. In both groups, before the start of the study and after the end of the liver ultrasound treatment course, the serum levels of liver enzymes including AST, ALT and ALP are evaluated and compared.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Non-alcoholic fatty liver based on ultrasound (grades 1 to 3) Age 18 to 70 years Informed consent of the patient; Exclusion criteria: Pregnancy or breastfeeding Alcoholic Fatty liver Smoking Taking hypoglycemic, hypolipidemic and anti-inflammatory drugs Other diseases such as viral hepatitis, coronary artery disease, kidney, lung and thyroid diseases

Intervention groups

The intervention group is given four 500 mg tablets daily (two in the morning and two at bedtime) of traditional medicine based on coriander, and the control group is given four 500 mg placebo tablets containing starch

powder for two months.

Main outcome variables

Fatty liver ultrasound grade, serum levels of ALT, AST and Alk-P enzymes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131214015790N3**

Registration date: **2020-12-06, 1399/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-06, 1399/09/16**

Update count: **0**

Registration date

2020-12-06, 1399/09/16

Registrant information

Name

Mehrzad Mehrbani

Name of organization / entity

School of Traditional Medicine, Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-05, 1399/09/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of traditional medicine based on Coriandrum sativum in comparison with placebo on the ultrasound grade and serum level of liver enzymes in patients with non-alcoholic fatty liver

Public title
Evaluation of the efficacy of a traditional product on fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of diagnosis of non-alcoholic fatty liver based on ultrasound (grades 1 to 3) Age 18 to 70 years
Written and informed consent of the patient
Exclusion criteria:
Pregnancy or breastfeeding Fatty liver secondary to alcohol consumption Smoking Taking hypoglycemic, hypolipidemic and anti-inflammatory drugs (any drug that affects liver function) Other diseases such as viral hepatitis, coronary artery disease, kidney, lung and thyroid diseases

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
This study is a double-blind clinical trial that is performed on patients with fatty liver in patients referred to Besat Clinic in Kerman in 1399. Patients are randomly assigned to the drug and placebo groups based on the quadruple block method.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the similarity of the drug and placebo, patients do not know which group they are in. On the other hand, drug and placebo coding is done by the pharmacist and the researcher is unaware of how patients are assigned to the groups until the end of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Research, Kerman University of Medical Sciences

Street address

Medical University Campus, Haft-Bagh Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-07-06, 1399/04/16

Ethics committee reference number

IR.KMU.REC.1399.261

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description

Fatty liver ultrasound grade

Timepoint

Beginning and end of the study (end of the second month)

Method of measurement

Ultrasound in the same radiology center

2

Description

Serum AST level

Timepoint

Beginning and end of the study (end of the second month)

Method of measurement

Beckman DU spectrophotometer

3

Description

Serum ALT level

Timepoint

Beginning and end of the study (end of the second month)

Method of measurement

Beckman DU spectrophotometer

4

Description

Serum Alk-P level

Timepoint

Beginning and end of the study (end of the second month)

Method of measurement

Beckman DU spectrophotometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group is given four tablets daily (two in the morning on an empty stomach and two at night at bedtime) of traditional medicine based on coriander for two months. These pills contain Coriandrum sativum seeds, Cichorium intybus L. seeds, Lactuca sativa seeds, Fumaria officinalis, Ziziphus jujuba, Zataria multiflora leaves, Cassia angustifolia leaves and Rheum palmatum root in equal proportions.

Category

Treatment - Drugs

2

Description

Control group: The control group is given four 500 mg placebo tablets (two in the morning on an empty stomach and two at night at bedtime) containing starch powder for two months.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Besat Clinic

Full name of responsible person

Mehrzaad Mehrbani

Street address

Ebn-e-Sina Ave., Jihad Blvd.

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7619813159

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

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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

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Mehrzaad Mehrbani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Latest degree

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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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available