

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the effect of plantago major with placebo on liver enzymes in patients with nonalcoholic fatty liver disease (NAFLD): a double-blind randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of Plantago major with placebo on liver enzymes in patients with nonalcoholic fatty liver disease: a double-blind randomized clinical trial

Design

Clinical trial with placebo, parallel groups, double blind, randomized

Settings and conduct

In this double-blind clinical trial, the effect of placebo on liver enzymes in non-alcoholic fatty liver patients was evaluated. Patients are randomly divided into two groups of case and control. Liver enzymes (ALT, AST) were measured at baseline and at 6th and 12th week. Both groups received dietary and exercise recommendations alike. Case group receive 2 grams Plantago major per day and the control group receive 2 grams of placebo daily capsules 500 mg. The drug and placebo are coded in similar capsules and in identical packages, with the same color and aroma, and the patient, clinician, and researcher are unaware of how the drug or placebo is coded.

Participants/Inclusion and exclusion criteria

Inclusion criteria Non Alcoholic Fatty Liver Disease (NAFLD) patients with liver enzymes rising (AST > 38, ALT > 40) and sonographic report grade 1 & 2 of fatty liver. Exclusion criteria Age between 12 - 80 years old Patient dislike to enter this study Pregnancy & lactation Anti coagulant drugs consumption Thyroid diseases Spleen diseases Cirrhosis, viral hepatitis and obstructive disease of liver Under treatment dyslipidemia Overt D.M Lung diseases History of Alcoholism Consumption of any drug that affects on liver enzymes and liver metabolism such as OCP, corticosteroids, salazins and ext.

Intervention groups

Intervention group: Plantago major seed, 2 grams daily,, Orally, For 12 weeks Control group: Placebo (Sokhari powder) 2 grams daily, , Orally, For 12 weeks

Main outcome variables

Comparison of changes in liver enzymes (ALT, AST) in non-alcoholic fatty liver patients in drug and placebo groups before and after the study.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191006044993N1**

Registration date: **2019-11-05, 1398/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-05, 1398/08/14**

Update count: **0**

Registration date

2019-11-05, 1398/08/14

Registrant information

Name

Seyedeh ferdos Jazayeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 1303

Email address

sf.jazayeri46@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of plantago major with placebo on liver enzymes in patients with nonalcoholic fatty liver disease (NAFLD): a double-blind randomized clinical trial

Public title
Effect of Plantago major on nonalcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Sono graphic report of Grade 1 and 2 fatty liver Increase in ALT> 40 Increase in AST>38 Ages 12 to 80 years
Exclusion criteria:
The patient's unwillingness to participate in the scheme Pregnancy & lactation Anti coagulant drugs consumption Thyroid diseases Spleen diseases Cirrhosis ,viral hepatitis and obstructive liver disease Treated dyslipidemia Overt Diabetes mellitus Lung diseases Taking any medication that affects liver metabolism and enzymes, including oral contraceptives, corticosteroids, salazines, etc.

Age
From **12 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method is used using 4-way blocks and a random number table. Interventions A and B define six blocks of four. Using random numbers, we select and write blocks. Each individual is then assigned to an A or B intervention. For allocation concealment, sealed envelopes are used, so that the individual number is written on the envelope and the treatment group inside the envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
The drug and placebo are coded in similar capsules and in identical packages, with the same color and aroma, and the patient, clinician, and researcher are unaware of how the drug or placebo is coded.

Placebo
Used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
No. 167, Mojahedine Eslam Ave., Behnam Towers
City
Tehran
Province
Tehran
Postal code
1154838346
Approval date
2019-07-20, 1398/04/29
Ethics committee reference number
IR.IUMS.REC.1398.412

Health conditions studied

1

Description of health condition studied
Non Alcoholic Fatty Liver Disease
ICD-10 code
K76-0
ICD-10 code description
Non Alcoholic Fatty Liver Disease

Primary outcomes

1

Description
Comprison of the Plantago major seed with Placebo on ALT enzyme (Alanin trasaminase) in Non Alcoholic Fatty Liver Disease (NAFLD)
Timepoint
Onset, 6th and 12th week of study. (End of study)
Method of measurement
Hitachi 912 instrument

2

Description
Comprison of the Plantago major seed with Placebo on AST enzyme (Aspartate transaminase) in Non Alcoholic Fatty Liver Disease (NAFLD)
Timepoint
Liver enzymes measurement at baseline, 6th and 12th weeks (end of study).
Method of measurement

Hitachi 912 instrument

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group in addition to lifestyle training and in-person follow-up once every 2 weeks, the 500 mg capsule of Plantago major seed twice per day is given, 2 capsules each time, orally for 12 weeks. The seeds of Plantago major are planted and placed in 500 mg capsules in the laboratory of the Faculty of Traditional Medicine.

Category

Treatment - Drugs

2

Description

Control group: In the intervention group in addition to lifestyle training and in-person follow-up once every 2 weeks, the 500 mg capsule of toasted flour twice per day is given, 2 capsules each time, orally for 12 weeks. After preparation, the bread powder was placed in 500 mg capsules in the laboratory of the Faculty of Traditional Medicine.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat-Rasool hospital

Full name of responsible person

Seyede Ferdos Jazayeri

Street address

No.167, Behnam Towers, Mojahedhne Eslam Ave.

City

Tehran

Province

Tehran

Postal code

1154838346

Phone

+98 21 7752 1303

Email

sf.jazayeri46@gmail.com

2

Recruitment center

Name of recruitment center

Behesht Persian Medicin clinic

Full name of responsible person

Seyede Ferdos Jazayeri

Street address

No.167, Behnam Towers, Mojahedhne Eslam Ave.

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Phone

+98 21 7752 1303

Email

sf.jazayeri46@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motevalian

Street address

Shahid Hemmat Highway, Iran University of Medical Science

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

admins@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Seyede Ferdos Jazayeri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

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Phone

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Email

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

Iran University of Medical Sciences

Full name of responsible person

Seyede Ferdos Jazayeri

Position

Resident

Latest degree

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

Iran University of Medical Sciences

Full name of responsible person

Seyede Ferdos Jazayeri

Position

Resident

Latest degree

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Other areas of specialty/work

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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