

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 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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## 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

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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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**Other areas of specialty/work**

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

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

Resident

**Latest degree**

Medical doctor

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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