Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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 recive 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 critria Non Alcoholic Fatty Liver Disease(NAFLD) pationts with liver enzymes rising (AST>38, ALT>40) and sonographic report grade 1&2 of fatty liver Exclusion critria 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 disese 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 disese 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.
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2

Recruitment center
Name of recruitment center
Behesht Persian Medicin clinic
Full name of responsible person
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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
Ṣhahid Hemmat Highway, Iran University of Medical Science
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1449614535
Phone
+98 21 86701
Email
adminsite@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 updating data

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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