Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Comparative study on the effect of Plantago Psyllium and Ocimum Basilicum seeds on body composition, blood sugar, lipid profile, liver enzymes, inflammatory index and sonografic finding in nonalcoholic fatty liver patients

Protocol summary

Summary

This randomized parallel trial aims to seek effects of fiber on prevention and improvement condition of patients with Nonalcoholic Fatty Liver Disease (NAFLD). We included fatty liver patients that NAFLD had been diagnosed by one specialist in Fatty Liver Clinic. In addition, our exclusion criteria were insulin injection, pregnant and lactating women, taking of some pills such as Corticosteroids, Anticonvulsants, and Antiepileptic, and steady using of fiber and antioxidant supplements. We selected 120 patients after assessing eligibility criteria and put them in 4 groups randomly. We couldn't blind the participants because they should sprinkle seeds in a glass of water and then drink them. But, the control group didn't receive placebo. Plantago Psyllium and Ocimum Basilicum seeds are two herbal seeds that are rich in fiber and especially mucilage. Studies showed controversial consequence of them. Also, we wanted to examine mixture of them that we thought has more efficiency in patients. We advised participants to use seeds twice daily, before lunch and before dinner for 3 month. We provided them in five-gram packages that patients should use them 20-30 minutes before while, they had been drenched in a glass of water. We are expecting mucilage fiber can reduce ALT, AST, Fatty Liver Grade, anthropometric measurements, and lipid profiles in different groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101811763N17**
Registration date: **2016-02-04, 1394/11/15**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-02-04, 1394/11/15

Registrant information

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Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-08-11, 1393/05/20

Expected recruitment end date

2015-01-01, 1393/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study on the effect of Plantago Psyllium and Ocimum Basilicum seeds on body composition, blood sugar, lipid profile, liver enzymes, inflammatory index and sonografic finding in nonalcoholic fatty liver patients

Public title
The comparative effect of Plantago Psyllium, Ocimum Basilicum seeds on non alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria: Males and females above 20 years nonalcoholic fatty liver that was confirmed at the first time by one specialist. exclusion criteria: Hemocromatosis; insulin injection; persistent use of Corticosteroids; alcohol abuse؛ pregnancy; lactation؛ Chronic inflammatory diseases; major operation in 6 months ago; fiber supplements
Age
From **20 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Nutrition Department, Hezar Jarib street, Isfahan, Iran
City
Isfahan
Postal code
Approval date
2014-10-18, 1393/07/26
Ethics committee reference number
393583

Health conditions studied

1

Description of health condition studied
Nonalcoholic Fatty Liver Disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
ALT,AST
Timepoint
first and the end of third month
Method of measurement
blood test

2

Description
ultrasound finding
Timepoint
first and the end of third month
Method of measurement
ultrasound

Secondary outcomes

1

Description
body compositon
Timepoint
first and the end of third month
Method of measurement
body composition analyser

2

Description
FBS, LDL, HDL, TG, TC
Timepoint
first and the end of third month
Method of measurement
blood test

Intervention groups

1

Description
10 grams of Plantago Psyllium, 5 grams before lunch and 5 grams before dinner with one glass of water during 3 month.
Category
Treatment - Other

2

Description
10 grams of Ocimum Basilicum, 5 grams before lunch and 5 grams before dinner with one glass of water during 3 month.
Category
Treatment - Other

3

Description
10 grams mixed of Ocimum Basilicum and Plantago Psyllium, 5 grams before lunch and 5 grams before dinner with one glass of water during 3 month.
Category
Treatment - Other

4

Description
The control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
The Research Center of Glands and Metabolism Hazrat Sedigheye Tahere
Full name of responsible person
Shahab Aldin Akbarian
Street address
Khoram street, Jomhori square, Isfahan
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Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Amir Mansour Alavi
Street address
Isfahan University of Medical Sciences, Hezar Jarib Street, Azadi Square, Isfahan, Iran
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Gholam Reza Askari
Position
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Person responsible for updating data

Contact
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Full name of responsible person

Shahab Aldin Kbarian

Position

Other areas of specialty/work

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Phone

00

Fax

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty