

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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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Name of organization / entity

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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 composition

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

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Khoram street, Jomhori square, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Amir Mansour Alavi

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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

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Position

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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