

# 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

###### Name

Gholamreza Askari

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2110

###### Email address

askari@mui.ac.ir

##### 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

##### Street address

Khoram street, Jomhori square, Isfahan

##### City

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

faculty

#### Other areas of specialty/work

#### Street address

Nutrition Department, Isfahan University of Medical  
Sciences, Hezar Jarib Street, Isfahan

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#### Phone

+98 31 3792 6000

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askari@mui.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences

#### Full name of responsible person

Gholam Reza Askari

#### Position

faculty

#### Other areas of specialty/work

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## Person responsible for updating data

### Contact

#### Name of organization / entity

#### Full name of responsible person

Shahab Aldin Kbarian

**Position**

**Other areas of specialty/work**

**Street address**

**City**

**Postal code**

**Phone**

00

**Fax**

**Email**

shahaab.akbarian@gmail.com

**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*