

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Effect of dark chocolate on serum levels of liver enzymes, inflammation and oxidative stress status in patients with non alcoholic fatty liver disease

#### Protocol summary

##### Summary

The aim of this study was to evaluate the effects of dark chocolate on the serum levels of protein reactive- C, liver enzymes, nuclear factor kappa B, malondialdehyde and total antioxidant capacity in patients with non-alcoholic fatty liver is. This study is a randomized and controlled study was performed on 42 patients. Patients were randomly divided into two groups: case group received a daily 30 mg of dark chocolate and control group was without consuming dark chocolate. The intervention period was 12 weeks. Variables including anthropometric indices, blood pressure, inflammatory markers, liver enzymes, fasting blood sugar and lipid profile were measured before and after intervention.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201303264545N2**

Registration date: **2014-12-25, 1393/10/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-12-25, 1393/10/04

##### Registrant information

###### Name

Pezhman Alavi nejad

###### Name of organization / entity

Ahvaz Jondishapur University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 1391 2533

##### Email address

ehajiani@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research institute for infectious diseases of digestive system, School of Medicine, Ahvaz Jundi Shapur University of Medical Sciences

##### Expected recruitment start date

2013-10-04, 1392/07/12

##### Expected recruitment end date

2013-12-31, 1392/10/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of dark chocolate on serum levels of liver enzymes, inflammation and oxidative stress status in patients with non alcoholic fatty liver disease

##### Public title

Non alcoholic fatty liver disease and dark chocolate

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 19-59 years old patient with non alcoholic fatty liver disease Exclusion criteria: Patients who have diabetes, cardiovascular, kidney and other hepatic diseases; Pregnant or lactating women; Smoking; Alcohol consumption; Use of dietary supplements.

##### Age

From **19 years** old to **60 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 42

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic commity of Ahvaz Jundishapur university of medical sciences

##### Street address

center of clinical researches, Ahvaz Jundishapur university of medical sciences

##### City

Ahvaz

##### Postal code

#### Approval date

2013-08-07, 1392/05/16

#### Ethics committee reference number

AJUMS.REC.1392.165

## Health conditions studied

### 1

#### Description of health condition studied

Non alcoholic fatty liver

#### ICD-10 code

K76.0

#### ICD-10 code description

Non alcoholic fatty liver disease

## Primary outcomes

### 1

#### Description

Nuclear factor-kappa B

#### Timepoint

Before intervention and 3 months after intervention

#### Method of measurement

ELISA

### 2

#### Description

Aspartate aminotransferase

#### Timepoint

Before intervention and 3 months after intervention

#### Method of measurement

ELISA

### 3

#### Description

High-sensitivity C-reactive Protein

#### Timepoint

Before intervention and 3 months after intervention

#### Method of measurement

ELISA

### 4

#### Description

Triglyceride

#### Timepoint

Before intervention, 3 month after intervention

#### Method of measurement

Photometric

### 5

#### Description

Malondialdehyde

#### Timepoint

Before intervention and 3 months after intervention

#### Method of measurement

ELISA

### 6

#### Description

Total antioxidant capacity

#### Timepoint

Before intervention and 3 months after intervention

#### Method of measurement

ELISA

### 7

#### Description

Alanine transaminase

#### Timepoint

Before intervention and 3 months after intervention

#### Method of measurement

ELISA

### 8

#### Description

VLDL

#### Timepoint

Before intervention and 3 month after intervention

#### Method of measurement

TG/5

## 9

### **Description**

LDL-C

### **Timepoint**

Before intervention and 3 months after intervention

### **Method of measurement**

Fridewald method

## 10

### **Description**

Fasting blood sugar

### **Timepoint**

Before intervention and 3 months after intervention

### **Method of measurement**

Photometric

## 11

### **Description**

HDL-C

### **Timepoint**

Before intervention and 3 month after intervention

### **Method of measurement**

Enzymatic

## **Secondary outcomes**

## 1

### **Description**

Body weight

### **Timepoint**

Before intervention and 3 month after intervention

### **Method of measurement**

Digital scale

## 2

### **Description**

Blood pressure

### **Timepoint**

Before intervention and 3 months after intervention

### **Method of measurement**

Blood pressure monitor

## 3

### **Description**

Body mass index

### **Timepoint**

Before intervention and 3 months after intervention

### **Method of measurement**

Body weight in kilograms divided by height squared in meters

## 4

### **Description**

Waist circumference

### **Timepoint**

Before intervention and 3 month after intervention

## **Method of measurement**

Meter

## 5

### **Description**

Hip circumference

### **Timepoint**

Before intervention and 3 month after intervention

### **Method of measurement**

Meter

## 6

### **Description**

Waist Hip Ratio

### **Timepoint**

Before intervention and 3 month after intervention

### **Method of measurement**

Waist circumference to hip Circumference ratio

## **Intervention groups**

## 1

### **Description**

Intervention group: daily consumption of 30 grams dark chocolate 83% (made by Iran Shirin Asal Company) for 3 months

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: without consuming dark chocolate for 3 months

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Education and Treatment Center Emam Khomeini Hospital

#### **Full name of responsible person**

Dr Pezhman Alavi Nejad

#### **Street address**

Ahvaz, Azadegan alley

#### **City**

Ahvaz

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Research Institute for Infectious Diseases of Digestive

System, Ahvaz Jundi Shapur University of Med

**Full name of responsible person**

Dr Pezhman alavi Nejad

**Street address**

Research Institute for Infectious Diseases of Digestive System, Imam hospital, Azadegan street

**City**

Ahvaz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Institute for Infectious Diseases of Digestive System, Ahvaz Jundi Shapur University of Med

**Proportion provided by this source**

**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*

**2**

**Sponsor**

**Name of organization / entity**

Shirin Asal Co.

**Full name of responsible person**

MRS Jale

**Street address**

Kaj Square, Saadat Abad

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shirin Asal Co.

**Proportion provided by this source**

**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**

Research Institute for Infectious Diseases of Digestive System, Ahvaz Jundi Shapur University of Med

**Full name of responsible person**

Farnaz farsi

**Position**

MSc in nutrition

**Other areas of specialty/work**

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Research Institute for Infectious Diseases of Digestive System, Ahvaz Jundi Shapur University of Med

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Dr Pezhman Alavi Nejad

**Position**

Gastroenterologist, Assistant professor

**Other areas of specialty/work**

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No. 16, 16th AVE., kianpars

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**Web page address**

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**Contact**

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**Position**

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+98 61 1292 1839

**Fax**

**Email**

farnaz.farsi@yahoo.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*