# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**
Triglyciride
**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 circumefrence
**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**

**Street address**
Ahvaz, Azadegan alley

**City**
Ahvaz

**Postal code**

**Phone**
+98 61 1292 1839

**Fax**

**Email**
farnaz.farsi@yahoo.com

**Web page address**

## Person responsible for scientific 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**
Dr Pezhman Alavi Nejad

**Position**
Gastroenterologist, Assistant professor

**Other areas of specialty/work**

**Street address**
No. 16, 16th AVE., kianpars

**City**
Ahvaz

**Postal code**
6155873559

**Phone**
+98 61 1391 2533

**Fax**

**Email**
pezhmanalavinejad@gmail.com

**Web page address**

## Person responsible for updating data

**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**
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**Other areas of specialty/work**

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**Postal code**

**Phone**
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**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*