

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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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

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Position

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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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