

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Effect of combined dietary weight loss and cranberry supplementation on hepatic enzymes, steatosis and inflammatory, antioxidant and apoptosis biomarkers in patients with Non-alcoholic fatty liver disease

Protocol summary

Study aim

the aim of this study is to determine the effect of combined dietary weight loss and cranberry supplementation on hepatic enzymes, steatosis and inflammatory, antioxidant and apoptosis biomarkers in patients with Non-alcoholic fatty liver disease.

Design

50 patients will be recruited. patients will be divided into two groups to take combined dietary weight loss and 2 capsules containing 288 mg Cranberry extract or placebo starch powder for 12 weeks. Randomization will be done using Blocked Randomization.

Settings and conduct

This randomized doubleblind, placebo-controlled, clinical trial will be conducted in Ahvaz Golestan hospital, Iran.

Participants/Inclusion and exclusion criteria

inclusion criteria: adult patients who were 18 years or older; evidence of NAFLD with a steatosis grade higher or equal to 2 in ultrasonography; serum alanine aminotransferase(ALT) greater than 30 IU/L for men and greater than 19 IU/L for women; Body mass index (BMI) Between 25 and 35 no history of alcohol consumption or consumption of less than 10 g of alcohol per day in women and less than 20 g/d in men; absence of other liver disorders, cardiovascular, respiratory, and kidney disorders; absence of pregnancy or lactation; absence of weight loss in the previous 3 months; and absence of endocrine and metabolism disorders.

Intervention groups

This is a randomized doubleblind, placebo-controlled, clinical trial. Intervention group: dietary weight loss and 2 capsules containing 288 mg Cranberry extract for 12 weeks Control group: dietary weight loss and 2 placebo capsules for 12 weeks

Main outcome variables

Fatty liver grade (Liver steatosis) ALT AST ALP Monocyte chemoattractant protein 1 (Mcp-1) ̢ CCL2 Citoceratine

18 Total antioxidant body (TAC) Malondialdehyde TNF̑
Lipid profile Fasting blood sugar Insulin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150124020765N2**

Registration date: **2019-01-06, 1397/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-06, 1397/10/16**

Update count: **0**

Registration date

2019-01-06, 1397/10/16

Registrant information

Name

Razie Hormoznejad

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 917 146 0816

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2019-04-23, 1398/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of combined dietary weight loss and cranberry supplementation on hepatic enzymes, steatosis and inflammatory, antioxidant and apoptosis biomarkers in patients with Non-alcoholic fatty liver disease

Public title

Effect of combined dietary weight loss and cranberry supplementation on Non-alcoholic fatty liver disease

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

adult patients who were 18 years or older evidence of NAFLD with a steatosis grade higher or equal to 2 in ultrasonography serum alanine aminotransferase(ALT) greater than 30 IU/L for men and greater than 19 IU/L for women Body mass index (BMI) Between 25 and 35

Exclusion criteria:

history of alcohol consumption or consumption of more than 10 g of alcohol per day in women and more than 20 g/d in men; Pregnancy or lactation History of other liver disorders, malignancies, cardiovascular, respiratory, and kidney disorders; Weight loss in the previous 3 months History of endocrine and metabolism disorders.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study; we assume equal allocation of subjects to each group With blocked randomization. With a randomized block design, the experimenter divides subjects in to subgroups called blocks, such that the variability within blocks is less than the variability between blocks. Then, subjects within each block are randomly assigned to treatment conditions.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researchers blind to the type of supplement given to each patient. A third party keep the identities of the subjects and which group (cranberry or placebo) they belong to, which are not revealed to researchers until the end of study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan highway

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2018-12-08, 1397/09/17

Ethics committee reference number

IR.AJUMS.REC.1397.678

Health conditions studied**1****Description of health condition studied**

Non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

Fatty liver grade (Steatosis)

Timepoint

At baseline and after 12 weeks

Method of measurement

ultrasonography

2**Description**

Alanine transaminase

Timepoint

At baseline and after 12 weeks

Method of measurement

enzymatic colorimetric assay

3

Description

Aspartate aminotransferase

Timepoint

At baseline and after 12 weeks

Method of measurement

Enzymatic colorimetric assay

4

Description

Alkaline phosphatase

Timepoint

At baseline and after 12 weeks

Method of measurement

Enzymatic colorimetric assay

5

Description

Monocyte chemoattractant protein 1 (Mcp-1) \downarrow CCL2

Timepoint

At baseline and after 12 weeks

Method of measurement

Elisa kit

6

Description

ytokeratin-18

Timepoint

At baseline and after 12 weeks

Method of measurement

Elisa kit

7

Description

Total antioxidant body

Timepoint

At baseline and after 12 weeks

Method of measurement

Elisa kit

8

Description

Malondialdehyde

Timepoint

At baseline and after 12 weeks

Method of measurement

Elisa kit

9

Description

Tumor necrosis factor alpha

Timepoint

At baseline and after 12 weeks

Method of measurement

Elisa kit

10

Description

Lipid profile

Timepoint

At baseline and after 12 weeks

Method of measurement

Elisa kit

11

Description

Insulin

Timepoint

At baseline and after 12 weeks

Method of measurement

Elisa

12

Description

Fasting blood sugar

Timepoint

At baseline and after 12 weeks

Method of measurement

Enzymatic colorimetric assay

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: dietary weight loss and 2 capsules containing 288 mg Cranberry extract for 12 weeks

Category

Other

2

Description

Control group: dietary weight loss and 2 placebo capsules for 12 weeks

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Ahvaz golestan hospital

Full name of responsible person

Razie Hormoznejad

Street address

Golestan hospital, Golestan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
dr Mohammad Badavi
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info@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Razie Hormoznejad
Position
Nutrition phd student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The results of this clinical trial will be published as an article after the end of the study

When the data will become available and for how long

Not specified

To whom data/document is available

Not specified

Under which criteria data/document could be used

An article

From where data/document is obtainable

Not specified

What processes are involved for a request to access data/document

Not specified

Comments