Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 formen and greater than19 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)) ų CCL2 Citoceratine 18 Total antioxidant body (TAC) Malondialdehyde TNFα 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
hormozi.r@ajums.ac.ir

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 formen and greater than19 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
Khouzestan
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)) ا 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
City
Ahvaz
Province

Khouzestan
Postal code
61357-15794
Phone
+98 61 3333 3777
Fax
Email
r_hormozi68@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
dr Mohammad Badavi
Street address
Golestan highway
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3331 1159
Email
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
Master
Other areas of specialty/work
Nutrition
Street address
Golestan highway
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 33333777
Email
r_hormozi68@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Razie Hormoznejad
Position
Nutrition Ph.d student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Golestan highway
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3311
Email
hormozi.r@ajums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Razie Hormoznejad
Position
Nutrition ph.d student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Golestan highway
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone

+98 61 3311

Email

r_hormozi68@yahoo.com

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