Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 2026

The study of effect of total anthocyanin base standardized (cornus mas L.) fruit extract on liver function, tumor necrosis factor α, malondealdehyde and adiponectin in patients with non-alcoholic fatty liver.

Protocol summary

Study aim

Objective: evaluating the effect of total anthocyanin base standardized (cornus mas L.) fruit extract on liver function, tumor necrosis factor α, malondealdehyde and adiponectin in patients with non-alcoholic fatty liver (NAFLD).

Design

Patients are randomly assigned into 2 groups (n=40 in each group) using a software to receive total anthocyanin base standardized (cornus mas L.) fruit extract (equal to 320 mg/d anthocyanins) or placebo daily for 12 weeks.

Settings and conduct

In a randomized double-blind clinical trial, 80 patients with NAFLD will be recruited from Diabetes Research Center, Shahid Sadoughi university of medical sciences, Yazd. The subjects are randomly divided into two groups to take total anthocyanin base standardized (cornus mas L.) fruit extract or placebo.

Participants/Inclusion and exclusion criteria

Study population: patients with NAFLD (n=80). Inclusion criteria: ALT levels more than 30 U / L in men and more than 19 U / L in women, age 25-26 years, the patients with grade 1, 2 and 3 fatty liver, the consent of subject to participate in the study, the patients are from Yazd. Exclusion criteria: The history of diseases including cirrhosis, viral hepatitis, cardiovascular disease, diabetes, Wilson and cancer; Consumption of medications including corticosteroids, nonsteroidal anti-inflammatory drugs, hypoglycemic agents, tamoxifen, sodium valproate, methotrexate, probiotics, any medicine or supplement that affect liver function, supplements with antioxidant and anti-inflammatory properties; Following a special diet; Pregnancy and breastfeeding; Alcohol consumption.

Intervention groups

Intervention group with total anthocyanin base standardized (cornus mas L.) fruit extract or placebo group.

Main outcome variables

Liver function (liver enzymes and cytokeratin-18 levels, liver steatosis and fibrosis); tumor necrosis factor α, malondealdehyde and adiponectin levels.

General information

Reason for update

A secondary outcome was modified without changing other sections of the protocol.

Acronym

IRCT registration information

IRCT registration number: **IRCT20180419039359N1**
Registration date: **2018-09-30, 1397/07/08**
Registration timing: **prospective**

Last update: **2021-11-23, 1400/09/02**
Update count: **2**

Registration date

2018-09-30, 1397/07/08

Registrant information

Name
Zohreh Sadat Sangsefidi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01
Expected recruitment end date
2019-06-22, 1398/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The study of effect of total anthocyanin base standardized (cornus mas L.) fruit extract on liver function, tumor necrosis factor α, malondealdehyde and adiponectin in patients with non-alcoholic fatty liver.

Public title
The study of effect of total anthocyanin base standardized (cornus mas L.) fruit extract in patients with non-alcoholic fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ALT levels more than 30 U / L in men and more than 19 U / L in women Age 25-26 years Diagnosis of the disease by ultrasonography and by a gastroenterologist The patients with grade 1, 2 and 3 fatty liver The consent of subject to participate in the study The patients are from Yazd
Exclusion criteria:
The history of diseases including cirrhosis, viral hepatitis, cardiovascular disease, diabetes, Wilson and cancer. Consumption of medications including corticosteroids, nonsteroidal anti-inflammatory drugs, hypoglycemic agents or any medicine that affect blood glucose, tamoxifen, sodium valproate, methotrexate, probiotics, any medicine or supplement that affect liver function, supplements with antioxidant and anti-inflammatory properties (such as vitamin D, vitamin E, omega-3, resveratrol) during 1 month before the study Following a special diet during 1 month before the study Pregnancy and breastfeeding شalcohol consumption
Age
From **25 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is performed using Random allocation software. Also, randomization is stratified by age gender.
Blinding (investigator's opinion)
Double blinded
Blinding description
The products ((cornus mas L.) fruit extract and placebo) are packed in the bottles that are same in terms of color, shape and size and labeled with "A" and "B" by an outside person who dose not know the details of the study. Therefore, participants and researchers will not be aware of the nature of the products in bottles.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences
Street address
Department of Nutrition, Faculty of Health, Shahid Sadoughi University of Medical Sciences ,Alam Square.
City
Yazd
Province
Yazd
Postal code
8915173160
Approval date
2018-03-17, 1396/12/26
Ethics committee reference number
IR.SSU.SPH.REC.1396.171

2

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences
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Department of Nutrition, Faculty of Health, Shahid Sadoughi University of Medical Sciences ,Alam Square.
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Approval date
2021-05-03, 1400/02/13
Ethics committee reference number
IR.SSU.SPH.REC.1400.020

Health conditions studied

1

Description of health condition studied
non-alcoholic fatty liver
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Serum levels of Alanine Aminotransferase (ALT)
Timepoint
Before and after the 12-week intervention
Method of measurement
By autoanalyzer

2

Description
Serum levels of Aspartate Aminotransaminase (AST)
Timepoint
Before and after the 12-week intervention
Method of measurement
By autoanalyzer

3

Description
Serum levels of Tumor necrosis factor α (TNF-α)
Timepoint
Before and after the 12-week intervention
Method of measurement
By ELISA kit

4

Description
Serum levels of Malondealdehyde (MDA)
Timepoint
Before and after the 12-week intervention
Method of measurement
By ELISA kit

5

Description
Serum levels of adiponectin
Timepoint
Before and after the 12-week intervention
Method of measurement
By ELISA kit

6

Description
Serum levels of cytokeratin-18 fragment M30 (CK-18 M30)
Timepoint
Before and after the 12-week intervention
Method of measurement
By ELISA kit

7

Description
Liver steatosis
Timepoint
Before and after the 12-week intervention
Method of measurement
By ultrasonography

8

Description
Liver fibrosis
Timepoint
Before and after the 12-week intervention
Method of measurement
By fibroscan

Secondary outcomes

1

Description
Fasting blood glucose (FBS)
Timepoint
Before and after the 12-week intervention
Method of measurement
By autoanalyzer

2

Description
Serum levels of Triglyceride (TG)
Timepoint
Before and after the 12-week intervention
Method of measurement
By autoanalyzer

3

Description
Serum levels of High-density lipoprotein (HDL)
Timepoint
Before and after the 12-week intervention
Method of measurement
By autoanalyzer

4

Description
Serum levels of Low-density lipoprotein (LDL)
Timepoint
Before and after the 12-week intervention
Method of measurement
By autoanalyzer

5

Description
Serum levels of total cholesterol
Timepoint
Before and after the 12-week intervention
Method of measurement
By autoanalyzer

6

Description
Serum levels of insulin
Timepoint
Before and after the 12-week intervention
Method of measurement
By ELISA kit

7

Description
Insulin resistance
Timepoint
Before and after the 12-week intervention
Method of measurement
By HOMA-IR and QUICKI

8

Description
Lipid accumulation product
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

9

Description
Atherogenic index of plasma
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

10

Description
Atherogenic coefficient
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

11

Description
Castelli 1 index
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

12

Description
Castelli 2 index
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

13

Description
TyG index
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

14

Description
Fatty liver index
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

15

Description
Hepatic steatosis index
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

16

Description
Visceral adiposity index
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

17

Description
NAFLD-liver fat score
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

18

Description
estimated glucose infusion rate
Timepoint
Before and after the 12-week intervention
Method of measurement
Formula

19

Description
Gamma glutamyl transpeptidase
Timepoint
Before and after the 12-week intervention
Method of measurement
By autoanalyzer

20

Description
Serum levels of E-selectin
Timepoint
Before and after the 12-week intervention
Method of measurement
By ELISA method

21

Description
Serum levels of Asymmetric dimethylarginine
Timepoint
Before and after the 12-week intervention
Method of measurement
By ELISA method

22

Description
Serum levels of nitric oxide
Timepoint
Before and after the 12-week intervention
Method of measurement
By ELISA method

23

Description
Seum levels of C reactive protein
Timepoint
Before and after the 12-week intervention
Method of measurement
By ELISA method

Intervention groups

1

Description
Intervention group: Daily intake of total anthocyanin base standardized (cornus mas L.) fruit extract (equal to 320 mg/d anthocyanins) for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: Daily intake of placebo for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Research Center, Shahid Sadoughi university of medical sciences, Yazd, Iran
Full name of responsible person
Dr. Saeed Hossein Khalilzadeh
Street address
Diabetes Research Center, Alley of Art Hall, Beginning of Bahonar Square to Azadi Square, Shahid Sadoughi Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Masoud Mirzaei
Street address
Shahid Sadoughi University of Medical Sciences, Bahonar Square
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Phone
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Fax
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Email
masoud_mirzaei@hotmail.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Zohreh Sadat Sangsefidi

Position

Ph.D. candidate on nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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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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Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

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Full name of responsible person

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Position

PhD candidate on Nutrition

Latest degree

Master

Other areas of specialty/work

Nutrition

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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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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