

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Sep 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 اش alcohol consumption

AgeFrom **25 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample sizeTarget 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.

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Yazd

Province

Yazd

Postal code

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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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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 Malondialdehyde (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

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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

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Full name of responsible person

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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

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Person responsible for general inquiries

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Name of organization / entity
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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

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