

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of cornelian cherry fruit extract on the inflammatory (IL-6) and oxidative (GPx) factors in patients with non-alcoholic fatty liver disease.

Protocol summary

Study aim

Effect of Cornus mas L. fruit extract on interleukin 6 and glutathione peroxidase in patients with non-alcoholic fatty liver disease.

Design

A parallel, double-blind, randomized clinical trial with 25 people in each group. Random allocation software is used.

Settings and conduct

50 patients suffering from non-alcoholic fatty liver disease are among the people who refer to the clinics affiliated to Shahid Sadoughi University of Medical Sciences, Yazd. Random allocation software is used for random allocation of people in groups. The products are labeled in similar colored bottles with the names A and B by someone outside the study who is unaware of the details of the study, and thus the participants and researchers will not know the nature of the products in the bottles.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ALT levels more than U/L 30 in men and more than U/L 19 in women, age 25-65 years, diagnosis of NAFLD, willingness and consent of the person to participate in the study, being a native of Yazd. Exclusion criteria: history of illness or any drug or supplement affecting blood sugar or liver; Having a special diet within 1 month before the study; pregnancy and breastfeeding; alcohol consumption.

Intervention groups

In the intervention group, people take 20 cc of the extract daily, and in the placebo group, people take 20 cc of the placebo.

Main outcome variables

inflammatory factor interleukin 6 (IL-6) and oxidative factor glutathione peroxidase (GPx)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220726055558N1**
Registration date: **2022-10-19, 1401/07/27**
Registration timing: **prospective**

Last update: **2022-10-19, 1401/07/27**

Update count: **0**

Registration date

2022-10-19, 1401/07/27

Registrant information

Name

Hassan Mozaffari khosravani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9121

Email address

h.mozaffari@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-29, 1401/09/08

Expected recruitment end date

2023-11-11, 1402/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of cornelian cherry fruit extract on the inflammatory (IL-6) and oxidative (GPx) factors in patients with non-alcoholic fatty liver disease.

Public title

Cornelian cherry fruit extract in patients with non-alcoholic fatty liver disease.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ALT levels more than U/L 30 in men a age 25-65 years diagnosis of NAFLD and patients with grade 1, 2 and 3 fatty liver willingness and consent of the person to participate in the study Being a native of Yazd ALT levels greater than U/L 19 in women

Exclusion criteria:

History of diseases including liver cirrhosis, viral hepatitis, cardiovascular diseases History of taking drugs, including corticosteroids, or any drug affecting blood sugar any drug or supplement affecting the liver within 1 month before the study history of following a specific diet within 1 month before the study breastfeeding and pregnancy alcohol consumption

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

People will be randomly assigned to intervention group with standardized blueberry fruit extract based on total anthocyanin or placebo group. Random allocation table created by Random allocation software and computer is used for random allocation of people in groups. Random allocation is also done in the form of stratified randomization based on age and gender.

Blinding (investigator's opinion)

Double blinded

Blinding description

After preparing the standardized cranberry fruit extract based on total anthocyanin and placebo, the products were packaged in similar colored bottles in terms of color, shape and size and named A and B by a person outside the study who is not aware of the details of the study. , are labeled, and thus participants and researchers will not know about the nature of the products in the bottles. The person measuring the indicators of the laboratory is not aware of receiving or not receiving the drug or placebo.

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, Yazd

Street address

Yazd- Shahid Dr. Bahnar Square- Central Organization of Shahid Sadoughi University of Medical Sciences and Healthcare Services, Yazd Shahid Sadoughi University of Medicine and Healthcare Services, Yazd-

City

yazd

Province

Yazd

Postal code

8916978477

Approval date

2022-04-24, 1401/02/04

Ethics committee reference number

IR.SSU.SPH.REC.1401.009

Health conditions studied

1

Description of health condition studied

People with non-alcoholic fatty liver with grades 1, 2, 3

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

2

Description of health condition studied

People with non-alcoholic fatty liver with grades 1, 2, 3

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Interleukin 6

Timepoint

Before the intervention and the end of the intervention after 12 weeks

Method of measurement

Measurement of plasma glutathione peroxidase by ELISA method

2

Description

Glutathione peroxidase

Timepoint

Before the intervention and the end of the intervention after 12 weeks

Method of measurement

Measurement of plasma glutathione peroxidase by ELISA method

Secondary outcomes

1

Description

Weight

Timepoint

Before the intervention and the end of the intervention after 12 weeks

Method of measurement

SECA scales

2

Description

waist circumference

Timepoint

Before the intervention and the end of the intervention after 12 weeks

Method of measurement

Inflexible meter

3

Description

hip circumference

Timepoint

Before the intervention and the end of the intervention after 12 weeks

Method of measurement

Inflexible meter

Intervention groups

1

Description

Intervention group: Intervention group: 20 cc (twice a day in the morning and at night for 12 weeks) of blueberry fruit extract (cornus mas L.) standardized on the basis of total anthocyanin (320 mg of anthocyanin), from the edible part of the blueberry fruit (cornus mas) L.) and is prepared in the pharmacology department of the Faculty of Pharmacy, Shahid Sadougi University of Medical Sciences, Yazd.

Category

Treatment - Drugs

2

Description

: Control group: In the placebo group, people receive the

same amount of extract from the placebo product as in the extract group. It will be 20 cc (twice a day in the morning and at night for 12 weeks). And it is prepared in the pharmacology department of the Faculty of Pharmacy, Shahid Sadougi University of Medical Sciences, Yazd.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Research Center and Special clinics affiliated to Shahid Sadougi University of Medical Sci

Full name of responsible person

Mr. Dr. Hassan Mozafari Khosravi

Street address

Yazd - Shahid Dr. Bahnar Square - Central Organization of Shahid Sadougi University of Medical Sciences and Health Services, Yazd

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dvc.research@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Ali Mohammad Moradi

Street address

Yazd - Shahid Dr. Bahnar Square - Central Organization of Shahid Sadougi University of Medical Sciences and Health Services, Yazd

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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

Mr. Dr. Hassan Mozafari Khosravi

Position

Dean of the Faculty of Health, Professor of the Nutrition Department, Director of the Nutrition Depa

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Yazd - Alam Square - Shahid Sadougi University of Medical Sciences and Health Services Campus - Faculty of Health

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Mr. Dr. Hassan Mozafari Khosravi

Position

The head of the Faculty of Health, the director of the nutrition department, the professor of the en

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data**Contact****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Mr. Dr. Hassan Mozafari Khosravi

Position

The head of the Faculty of Health, the director of the nutrition department, the professor of the en

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

No - There is not a plan to make this available

When the data will become available and for how long

No - There is not a plan to make this available

To whom data/document is available

No - There is not a plan to make this available

Under which criteria data/document could be used

No - There is not a plan to make this available

From where data/document is obtainable

No - There is not a plan to make this available

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

No - There is not a plan to make this available

Comments