Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Sep 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)

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+98 35 3820 9121

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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 Sadoughi 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 Sadoughi 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 Sadoughi 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
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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
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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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ravabet.odb@ssu.ac.ir

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
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Other areas of specialty/work
Nutrition
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ravabet.odb@ssu.ac.ir

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