Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Sep 2026

Evaluation of the efficacy of Cranbery in management of non-alcoholic Fatty Liver Patients

Protocol summary

Study aim
Determining the effect of cranberry extract on the response to treatment regimen of fatty liver patients on liver enzymes, ultrasound grade, lipid profile and serum glucose levels

Design
The study was an intervention and participants will receive cranberry extract and placebo as a double-sided blind and data analyzer will also be blind. The sample size will be 80 people who will receive 50% of the sample volume of cranberry extract and 50% placebo for 6 months and then will be analyzed.

Settings and conduct
The study will be performed in the specialized clinic of Imam Reza Hospital in Tabriz. Participants will receive cranberry extract and placebo as a double-sided blind and data analyzer will also be blind.

Participants/Inclusion and exclusion criteria
Entry conditions: Patients with non-alcoholic fatty liver grade 1, 2 and 3 Patients with newly diagnosed fatty liver Candidates for fatty liver treatment No entry conditions: Patient dissatisfaction Rule out the diagnosis of fatty liver

Intervention groups
Intervention group: The first intervention group includes patients with grade 1, 2 and 3 liver who will receive one cranberry extract daily for 6 months. Control group: The second intervention group includes patients with grade 1, 2 and 3 liver who will receive one plasebo daily for 6 months.

Main outcome variables
Determination of lipid profile level before and after cranberry and placebo use Determination of serum insulin and fasting glucose levels before and after cranberry and placebo Determination of Ultrasound grade before and after cranberry and placebo Determination of serum levels of liver enzymes before and after cranberry and placebo

General information

Reason for update
for increasing generalizability of result all patients with NAFLD (grade 1-3) were included. moreover, some confounding factors that affect the result of the study were considered as exclusion criteria such as alcohol consumption and use of vitamin and antioxidant supplements. we sampled more than anticipated number, 94 patients

Acronym

IRCT registration information
IRCT registration number: **IRCT20200725048200N1**
Registration date: **2020-08-11, 1399/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-27, 1400/04/06**
Update count: **2**

Registration date
2020-08-11, 1399/05/21

Registrant information

Name
Elham Shirinpour

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
2020-07-27, 1399/05/06

Expected recruitment end date
2021-07-28, 1400/05/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Cranbery in management of non-alcoholic Fatty Liver Patients

Public title

Evaluation of the efficacy of Cranbery in treatment of Fatty Liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with non-alcoholic fatty liver grade1, 2 and 3 Patients with newly diagnosed fatty liver Candidates for fatty liver treatment

Exclusion criteria:

Patient dissatisfaction Rule out the diagnosis of fatty liver Drug intolerance Existence of diabetes, , heart, renal and pulmonary failure, other liver diseases in which fatty liver appears in the picture alcohol consumption antioxidant and vitamins supplements other that vitamin E pregnant and lactating mothers

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **94**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will receive cranberry extract and placebo as a double-sided blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht St., in front of the Central University Organization, Imam Reza Educational and Medical Center

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2020-04-20, 1399/02/01

Ethics committee reference number

IR.TBZMED.REC.1399.090

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

Determination of lipid profile level before and after cranberry and placebo use

Timepoint

Study time and 6 months after taking cranberry extract and placebo

Method of measurement

Perform blood tests

2

Description

Determination of serum insulin and fasting glucose levels before and after cranberry and placebo

Timepoint

Study time and 6 months after taking cranberry extract and placebo

Method of measurement

Perform blood tests

3

Description

Determination of Ultrasound grade before and after cranberry and placebo

Timepoint

Study time and 6 months after taking cranberry extract

and placebo

Method of measurement

Ultrasound device

4

Description

Determination of serum levels of liver enzymes before and after cranberry and placebo

Timepoint

Study time and 6 months after taking cranberry extract and placebo

Method of measurement

Perform blood tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first intervention group includes patients with grade 1, 2 and 3 liver.Cranberry extract is called Cranberry Shari, which is the brand name.Ingredients of its formulation 144 mg of cranberry fruit extract (Vaccinium Macrocarporn)،Standardized based on the presence of 25% proanthocyanidin، Equivalent to 36 mg of active ingredient (equivalent to 13 g of dried cranberry fruit).Patients will receive one daily, preferably with food, for 6 months. Possible side effects of the drug include gastrointestinal disorders (nausea and vomiting) and diarrhea (if taken in large amounts) explained to patients in the first session and then in the next sessions the referral will be asked about its possibility.

Category

Treatment - Drugs

2

Description

Control group: The second intervention group includes patients with grade 1, 2 and 3 liver who will receive one placebo daily for 6 months. The duration of use, the manner of consumption of patient education and follow-up of patients will be completely according to the patients receiving the main drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza hospital

Full name of responsible person

Elham Shirinpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gastrointestinal and Liver Diseases Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad hossein Somi

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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

Gastrointestinal and Liver Diseases Research Center, Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Kourosh Masnadi shirazi nezhad
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
In this study, patients' identities are not shared.
When the data will become available and for how long
Access period starts 12 months after the results are published.
To whom data/document is available
Data will only be available to researchers in this study.
Under which criteria data/document could be used
The data will be available to researchers only for meta-analysis study and for data analysis.
From where data/document is obtainable
Receipt of data will be done through the scientific respondent of the study.
What processes are involved for a request to access data/document
To receive the data, an email is sent to the scientific respondent and the reason for receiving the data is mentioned in detail and if the reasons are appropriate, the information will be sent.
Comments