Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the simultaneous effect of high global diet quality score and standard diet with and without artichoke supplementation on fasting blood sugar, lipid profile and liver function indices in patients with non-alcoholic fatty liver disease: a randomized clinical trial

Protocol summary

Study aim

Determining the simultaneous effect of high global diet quality score and standard diet with and without artichoke supplementation on fasting blood sugar, lipid profile and liver function indices in patients with non-alcoholic fatty liver disease.

Design

The present study will be conducted with a 2 by 2 parallel design in order to investigate compliance with the GDQS diet and artichoke supplement consumption in 4 groups and each group will include 25 people with non-alcoholic fatty liver disease for 8 weeks.

Settings and conduct

Non-alcoholic fatty liver,in Ilam city The participants are randomly divided into 4 groups GDQS diet + supplement, GDQS diet + placebo, standard diet + supplement, standard diet + placebo. The intervention and control groups will receive three artichoke capsules and three placebo capsules daily for eight weeks. Anthropometric indicators including weight, height and waist circumference, physical activity level using IPAQ questionnaire, compliance with the GDQS diet using a three-day food diary and fatty liver grade Non-alcoholic will be evaluated using sonographic findings as well as biochemical tests

Participants/Inclusion and exclusion criteria

People diagnosed with hepatic steatosis (grades 1 to 3) based on liver ultrasound are selected from among adults aged 18 and above referring to gastroenterology and liver clinics. Non-entry criteria include pregnancy or breastfeeding؛ hepatitis؛ coronary؛ kidney؛ lung؛ and thyroid diseases.

Intervention groups

Individuals will be randomly assigned to one of four groups as follows. First group: GDQS diet + supplement, second group: GDQS diet + placebo, third group: standard diet + supplement, fourth group: standard diet + placebo.

Main outcome variables

sonographic findings; liver enzymes ALT and AST; anthropometric indicators of weight, waist circumference and BMI; fasting blood sugar; LDL-c; HDL-c; TG

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240310061235N1**
Registration date: **2024-06-20, 1403/03/31**
Registration timing: **prospective**

Last update: **2024-06-20, 1403/03/31**
Update count: **0**

Registration date

2024-06-20, 1403/03/31

Registrant information

Name

Mona Jamalvandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3149 2240

Email address

m.jamalvandi71@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the simultaneous effect of high global diet quality score and standard diet with and without artichoke supplementation on fasting blood sugar, lipid profile and liver function indices in patients with non-alcoholic fatty liver disease: a randomized clinical trial

Public title

Investigating the effect of high global quality of diet and artichoke supplement in non-alcoholic fatty liver disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years Suffering from non-alcoholic fatty liver grade 1-3

Exclusion criteria:

Pregnancy or breastfeeding suffering from hepatitis, coronary, kidney, lung and thyroid diseases

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation between two groups will perform using Random allocation version 2 software. The random sequence will generate with this software using a simple random allocation method, and each number will allocate to an intervention group A or B. Allocation concealment will perform by calling or sending message to a third-person who is unaware of intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants, investigators and data collectors will be blinded to the study groups. Allocation concealment will perform by calling or sending message to a third-person who is unaware of intervention.

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

School of public health, Shahid Sadoughi University of Medical Sciences, Shohadaye Gomnam Blvd., Alam Square, Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2024-06-10, 1403/03/21

Ethics committee reference number

IR.SSU.SPH.REC.1403.064

Health conditions studied

1

Description of health condition studied

Patients with non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Nonalcoholic fatty liver disease [NAFLD]

Primary outcomes

1

Description

Fatty liver grade

Timepoint

The beginning and end of the study

Method of measurement

Ultrasound machine

2

Description

Liver enzymes (ALT, AST)

Timepoint

The beginning and end of the study

Method of measurement

Biochemical test

3

Description

Fasting blood glucose

Timepoint
The beginning and end of the study
Method of measurement
Biochemical test

4

Description
Lipid profile (LDL-c, HDL-c, TG)
Timepoint
The beginning and end of the study
Method of measurement
Biochemical test

Secondary outcomes

1

Description
Weight
Timepoint
The beginning and end of the study
Method of measurement
scale

2

Description
Waist
Timepoint
The beginning and end of the study
Method of measurement
tape measure

3

Description
Food intake
Timepoint
The beginning and end of the study
Method of measurement
24-hour feed reminder

4

Description
physical activity
Timepoint
The beginning and end of the study
Method of measurement
IPAQ questionnaire

Intervention groups

1

Description
The first intervention group
Category
Treatment - Drugs

2

Description
The second intervention group
Category
Treatment - Drugs

3

Description
The third intervention group
Category
Treatment - Drugs

4

Description
Control group:
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ultrasound clinic and internal specialist in Ilam
Full name of responsible person
Dr. Seyed Saeed Khayatzadeh
Street address
Taleghani
City
Ilam
Province
Ilam
Postal code
6931311111
Phone
+98 918 587 7499
Email
m.jamalvandi71@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amin Salehi Abargouei
Street address
Daneshjoo Blv
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3628 8114
Email

dvc.research@ssu.ac.ir

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

Mona Jamalvandi

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition, Faculty of Health, Shahid Sadoughi University of Medical Sciences, Alam Square, Yazd City

City

yazd

Province

Yazd

Postal code

8916188637

Phone

+98 35 3820 9100

Email

m.jamalvandi71@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Sayyed Saeid Khayyatzadeh

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition, Faculty of Health, Shahid Sadoughi University of Medical Sciences, Alam Square, Yazd City

City

yazd

Province

Yazd

Postal code

8916188637

Phone

+98 35 3820 9100

Email

khayyatzadeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mona Jamalvandi

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Department of Nutrition, Faculty of Health, Shahid Sadoughi University of Medical Sciences, Alam Square, Yazd City

City

yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3149 2228

Email

m.jamalvandi71@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

primary outcome will be available at the end of study

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Academic institutes can send their official request to the email of the scientific director of the project. the data will be sent after confirmation of ethics committee of shahid sadoughi university of medical sciences. It is not possible to perform statistical analysis on the data.

From where data/document is obtainable

Sayyed Saeid Khayyatzadeh Assistant professor of nutrition in Shahid Sadoughi university of medical sciences Khayyatzadeh@yahoo.com 00983538209100

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

Academic institutes can send their official request to the email of the scientific director of the project. The data will be sent after confirmation of ethics committee of Shahid Sadoughi university of medical sciences

Comments