

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of a diet based on vegetable and dairy protein on serum levels of inflammatory biomarkers and oxidative stress in patients with liver cirrhosis: a randomized controlled trial

Protocol summary

Study aim

Evaluating the effect of a diet based on vegetable and dairy protein on serum levels of inflammatory biomarkers and oxidative stress in patients with liver cirrhosis

Design

A randomized controlled clinical trial with parallel groups

Settings and conduct

The intervention will be carried out on adults with liver cirrhosis who are eligible for the study, referring to gastroenterology clinics in Tehran. Subjects will be randomly divided into intervention and control groups and will be studied for 12 weeks. Blinding will not be done for any of the participants and researchers due to the nature of the diet.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosed liver cirrhosis for at least 6 months; Age range from 30 to 60 years; Willingness to participate in the study Exclusion criteria: MELD score greater than 18 or Child-Pugh Class C; Active gastrointestinal bleeding; Serum creatinine above 1.5 mg/dl during the last month; Alcohol consumption and tobacco use during the last 6 months; Pregnancy and lactation; Suffering from diabetes, pulmonary diseases, psychological disorders, hepatocellular carcinoma and other cancers, heart failure, acute viral hepatitis, cholestatic cirrhosis, autoimmune cirrhosis, other autoimmune diseases, hyperuricemia, and musculoskeletal diseases Taking corticosteroids and immunosuppressive medications

Intervention groups

Subjects in both groups will receive a diet in which energy will be 1.3 times of resting energy expenditure, protein will be 1.2 g/Kg, and fat and carbohydrates will be 30 and 50-55% of total calories, respectively for 12 weeks. The dietary protein source in the intervention group will be based on vegetable and dairy proteins. In the control group, the required protein will be provided

from all food groups.

Main outcome variables

Inflammatory biomarkers; oxidative stress status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220426054667N3**

Registration date: **2023-07-02, 1402/04/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-02, 1402/04/11**

Update count: **0**

Registration date

2023-07-02, 1402/04/11

Registrant information

Name

Somayyeh Asghari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5814

Email address

sasghari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-21, 1402/03/31

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a diet based on vegetable and dairy protein on serum levels of inflammatory biomarkers and oxidative stress in patients with liver cirrhosis: a randomized controlled trial

Public title

The effect of a diet based on vegetable and dairy protein in patients with liver cirrhosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having liver cirrhosis with a doctor's diagnosis for at least 6 months Age range from 30 to 60 years Willingness to participate in the study

Exclusion criteria:

Model for End-Stage Liver Disease (MELD) score greater than 18 or Child-Pugh Class C Active gastrointestinal bleeding Serum creatinine above 1.5 mg/dl during the last month Consumption of alcohol and tobacco during the last 6 months Pregnancy and lactation Suffering from diabetes, pulmonary diseases, psychological disorders, hepatocellular carcinoma and other cancers, heart failure, acute viral hepatitis, cholestatic cirrhosis, autoimmune cirrhosis, other autoimmune diseases, hyperuricemia, musculoskeletal diseases Taking corticosteroids and immunosuppressive medications

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to two groups using permuted block randomization with size 2, whose random sequence is generated using RAS software, including the intervention group (receiving a diet based on vegetable and dairy protein) and the control group (receiving a standard isocaloric diet).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine- Tehran University of Medical Sciences

Street address

Room 605, Sixth Floor, Central Building of Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.

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Tehran

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Postal code

1417653911

Approval date

2023-04-19, 1402/01/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.048

Health conditions studied**1****Description of health condition studied**

Liver Cirrhosis

ICD-10 code

K74.6

ICD-10 code description

Other and unspecified cirrhosis of liver

Primary outcomes**1****Description**

Weight

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Digital scale

2**Description**

Height

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Stadiometer

3**Description**

Body Mass Index (BMI)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Body weight (kilogram) divided by the square of height (meter)

4**Description**

Mid Arm Circumference (MAC)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Tape

5**Description**

Triceps skin fold (TSF)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Caliper

6**Description**

Middle Arm Muscle Circumference (MAMC)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

MAC - $(3.1416 \times \text{TSF})$ formula

7**Description**

Interleukin 6

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

ELISA

8**Description**

Tumor necrosis factor alpha (TNF- α)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

ELISA

9**Description**

High-sensitivity C-reactive protein (hsCRP)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Immunoturbidometry

10**Description**

Malondialdehyde (MDA)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Spectrophotometry

11**Description**

Total antioxidant capacity (TAC)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Spectrophotometry

12**Description**

Total bilirubin

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Photometric

13**Description**

Prothrombin time (PT)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Biochemical kit

14**Description**

Model for End-Stage Liver Disease score

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

The Model for End-Stage Liver Disease score is calculated using serum bilirubin, serum creatinine, and International Normalized Ratio (INR) and is given by the formula: $9.57 \times \log_e(\text{creatinine}) + 3.78 \times \log_e(\text{total bilirubin}) + 11.2 \times \log_e(\text{International Normalized Ratio}) + 6.43$

15**Description**

Total oxidant status (TOS)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Spectrophotometry

16**Description**

Creatinine

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

Jaaffe/colorimetric

17

Description

International Normalized Ratio (INR)

Timepoint

Before intervention and 12 weeks after the intervention

Method of measurement

[patient PT (s)/MNPT (s)] ISI Formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A diet based on vegetable and dairy protein. Based on the latest guidelines, in this diet, energy will be calculated 1/3 times REE (using the Harris-Benedict equation), protein will be 1/2 gram per kilogram of body weight, fat will be 30% of total calories, and carbohydrate will be 50-55% of total calories. Then, the required amounts of each food group will be determined, and based on that, a menu of 3 meals and 4 snacks will be prepared and presented to the patient. Patients will follow the prescribed diet for 12 weeks. Patients also will be educated about food alternatives. The protein requirement in this diet will be provided from bread and cereals, vegetables, legumes, soy and soy milk, nuts, and dairy products.

Category

Treatment - Other

2

Description

Control group: Standard diet. Based on the latest guidelines, in this diet, energy will be calculated 1/3 times REE (using the Harris-Benedict equation), protein will be 1/2 gram per kilogram of body weight, fat will be 30% of total calories, and carbohydrate will be 50-55% of total calories. Then, the required amounts of each food group will be determined, and based on that, a menu of 3 meals and 4 snacks will be prepared and presented to the patient. Patients will follow the prescribed diet for 12 weeks. Patients also will be educated about food alternatives. The protein requirement in this diet will be provided from bread and cereals, vegetables, legumes, all kinds of meat, eggs, dairy, and nuts.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Somayyeh Asghari

Street address

Shariati Hospital, Jalal-e-Al-e-Ahmad Highway, North Kargar Ave

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Web page address

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2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Mohammad Taher

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Imam Khomeini Hospital Complex, Dr. Gharib Ave ;at the end of Keshavarz Boulevard,Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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6th floor of Research and Technology Vice-Chancellor., Central Organization of the University.,Keshavarz Blvd., corner of Quds St

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Somayyeh Asghari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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

Tehran University of Medical Sciences

Full name of responsible person

Somayyeh Asghari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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

Tehran University of Medical Sciences

Full name of responsible person

Banafshe Khalese Ranjbar

Position

Student

Latest degree

Bachelor

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to the confidentiality of the participants' information,
it is not possible to publish it

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable