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)

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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.
City
Tehran
Province
Tehran
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 × 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 × loge (creatinine) + 3.78 × loge (total bilirubin) + 11.2 × loge (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
Jaafe/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
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Shariati Hospital, Jalal-e-Al-e-Ahmad Highway, North Kargar Ave
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2

Recruitment center
Name of recruitment center
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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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Email
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Web page address
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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
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Other areas of specialty/work
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Person responsible for updating data

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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