Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of a diet based on vegetable and dairy protein on biochemical and functional indicators of sarcopenia 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 compared to a standard diet on biochemical and functional indicators of sarcopenia in patients with liver cirrhosis

Design
A randomized, controlled, parallel-group, phase 3 clinical trial on 50 patients.

Settings and conduct
The intervention will be carried out for 12 weeks on people with liver cirrhosis in specialized gastroenterology clinics in Tehran. Face-to-face meetings will be held once every three weeks. Evaluation of variables at the beginning and end of the study will be done.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosed liver cirrhosis for at least 6 months, age between 30 and 60 years old, and Willingness to participate in the study. Exclusion criteria: MELD score >18 or Child-Pugh Class C, Active gastrointestinal bleeding, Serum creatinine >1.5 mg/dl during the last month, Alcohol and tobacco consumption 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.

Intervention groups
Subjects in both groups will receive a diet in which energy will be 1.3 times REE, protein will be 1.2g/Kg, and fat and carbohydrates will be 30 and 50-55% of total calories, respectively. 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 including bread and grains, vegetables, legumes, meats, eggs, dairy, and nuts.

Main outcome variables
Muscle function, myostatin, severity of malnutrition, severity of disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220426054667N2**
Registration date: **2023-06-08, 1402/03/18**
Registration timing: **prospective**

Last update: **2023-06-08, 1402/03/18**
Update count: **0**

Registration date
2023-06-08, 1402/03/18

Registrant information

Name
Somayyeh Asghari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
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Email address
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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 biochemical and functional indicators of sarcopenia 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

Prevention

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:

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 and tobacco consumption 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 will be randomly assigned to two groups including the intervention group (receiving a diet based on plant and dairy protein) and the control group (receiving a standard isocaloric diet). Randomization will be carried out using a permuted block randomization procedure of size 2, whose random sequence is generated using RAS software. The people of the two groups will be matched in terms of age, gender and severity of malnutrition.

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

2023-04-30, 1402/02/10

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.060

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

Myostatin

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

ELISA

2

Description

4-metre Gait Speed Test

Timepoint

Baseline and after 12 weeks of intervention

Method of measurement

chronometer

3

Description
Five Times Sit to Stand Test
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Chronometer

4

Description
Handgrip strength
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Dynamometer

5

Description
Weight
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Digital scale

6

Description
Body Mass Index (BMI)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Weight (Kg)/height(m)2

7

Description
Middle Arm Circumference (MAC)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Tape

8

Description
Triceps skin fold (TSF)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Caliper

9

Description
Middle Arm Muscle Circumference (MAMC)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
MAMC = MAC – (3.1416 × TSF)

10

Description
Ammonia
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Biochemical kit

11

Description
Total bilirubin
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Photometric

12

Description
Prothrombin time (PT)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Biochemical kit

13

Description
Model for End-Stage Liver Disease
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Formula: 9.57 × loge (creatinine) + 3.78 × loge (total bilirubin) + 11.2 × loge (INR) + 6.43

14

Description
Serum creatinine
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Jaafe

15

Description
International Normalized Ratio (INR)
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Formula: INR = [patient PT (s)/MNPT (s)] ISI

16

Description
Albumin
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Special kit

17

Description
Total protein
Timepoint
Baseline and after 12 weeks of intervention
Method of measurement
Biochemical kit

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 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 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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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, Tohid Squre
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Street address
Central Building of Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.
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Postal code
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Email
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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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No. 44, Shahid Hojjat Doost Alley, Naderi St, Keshavarz Boulevard

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Person responsible for scientific inquiries

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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

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Student

Latest degree
Master

Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable