

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

+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 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: $9.57 \times \log_e(\text{creatinine}) + 3.78 \times \log_e(\text{total bilirubin}) + 11.2 \times \log_e(\text{INR}) + 6.43$

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: $\text{INR} = [\text{patient PT (s)}/\text{MNPT (s)}] \text{ ISI}$

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

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 2888

Email

sasghari@sina.tums.ac.ir

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Mohammad Taher

Street address

Imam Khomeini Hospital Complex, Tohid Squire

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Phone

+98 21 6119 0000

Email

tahermdir@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Central Building of Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Email

afotouhi@tums.ac.ir

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

Tehran

Province

Tehran

Postal code

1416643931

Phone

0098 21 889900285

Email

asghari.nut@gmail.com

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

Street address

No. 44, Shahid Hojjat Doost Alley, Naderi St,
Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1416643931

Phone

0098 21 889900285

Email

asghari.nut@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdiyeh Taghizadeh

Position

Student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

No. 9, Meraj Aly ., Sahandiyeh Ave., Ashrafiyeh Laleh
Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5175678688

Phone

0098414757177

Email

mahdiyeh Taghizadeh9969@gmail.com

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

Street address

No. 44, Shahid Hojjat Doost Alley, Naderi St,
Keshavarz Boulevard

City

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