Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the Impact of CAPRIDIN Consumption Containing Medium-Chain Fatty Acids on Biochemical Metabolic Pathways and Inflammatory Responses in Individuals Affected by Metabolic Associated Steatotic Liver Disease (MASLD)

Protocol summary

Study aim
Investigating the Impact of CAPRIDIN Consumption on Biochemical Metabolic Pathways and Inflammatory Responses in Patients with Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD).

Design
A clinical trial with a control group, with parallel groups, non-blinded, randomized, phase 1-2 on 20 patients.

Settings and conduct
Certainly! In this ongoing study, twenty patients diagnosed with MASLD, aged 15 to 65 years, are selected from the specialized gastroenterology clinic at Taleghani Hospital. After evaluating entry criteria, the intervention group receives CAPRIDIN (a product from Kondor Pharma, Canada) for two months, taking 0.5 milliliters per kilogram of body weight daily while fasting. The intervention group is advised to limit carbohydrate sources in their daily diet. General dietary guidelines for reducing carbohydrate intake are provided. The control group also receives education on dietary control and lifestyle, and blinding is not implemented in this study

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients with metabolic dysfunction-associated steatotic liver disease (MASLD), confirmed by a specialist physician based on laboratory results and imaging, within the age range of 15 to 65 years ;Exclusion Criteria: Previous consumption of any ketogenic diets, alcohol use, and pregnancy

Intervention groups
Patients assigned to the intervention group receive a daily dose of 0.5 milliliters of CAPRIDIN per kilogram of body weight, along with their meals, for two months. Patients in the control group do not consume any CAPRIDIN during this period

Main outcome variables
Serum alanine aminotransferase (ALT) level.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170315033086N12**
Registration date: **2024-09-19, 1403/06/29**
Registration timing: **prospective**

Last update: **2024-09-19, 1403/06/29**
Update count: **0**

Registration date
2024-09-19, 1403/06/29

Registrant information

Name
Saeed Karima

Name of organization / entity
Shahid Beheshti University of Medical Sciences (SBMU)

Country
Iran (Islamic Republic of)

Phone
+98 21 9666 1028

Email address
karima@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2025-09-23, 1404/07/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Impact of CAPRIDIN Consumption Containing Medium-Chain Fatty Acids on Biochemical Metabolic Pathways and Inflammatory Responses in Individuals Affected by Metabolic Associated Steatotic Liver Disease (MASLD)

Public title

Investigating the effect of CAPRIDIN in the treatment of metabolic fatty liver

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals diagnosed with Metabolic Associated Steatotic Liver Disease based on laboratory results, imaging techniques, and specialist physician confirmation.

Exclusion criteria:

Any previous consumption of the ketogenic diets History of alcohol consumption pregnancy

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly allocate patients to the intervention and control groups, the “Random Allocation V.2” software (available for download at https://random-allocation-software.software.informer.com) will be used. In this study, block randomization with a block size of 4 will be employed. This means that patients will be randomly assigned to the intervention and control groups in blocks of 4. In this study, there are 20 participants, with 10 in the intervention group and 10 in the control group

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

Ethics Committee of Faculty of Medicine, Shahid Beheshti University of Medical Sciences and Healths

Street address

Shahid Chamran highway - Evin - next to Taleghani hospital - medical school - ground floor

City

Tehran

Province

Tehran

Postal code

1985717434

Approval date

2024-07-31, 1403/05/10

Ethics committee reference number

IR.SBMU.MSP.REC.1403.268

Health conditions studied

1

Description of health condition studied

Metabolic dysfunction-associated steatotic liver disease

ICD-10 code

K75.8

ICD-10 code description

Other specified inflammatory liver diseases, Nonalcoholic steatohepatitis [NASH]

Primary outcomes

1

Description

Serum alanine aminotransferase level

Timepoint

One time at the beginning of the study and one time after two months

Method of measurement

Enzymatic method

2

Description

Serum level of interleukin 1 beta

Timepoint

One time at the beginning of the study and one time after two months

Method of measurement

Elisa method

Secondary outcomes

empty

Intervention groups

1

Description
Patients with Metabolic dysfunction–associated steatotic liver disease (MASLD) who, following a comprehensive education session about the composition, on average consume 0.5 milliliters of CAPRIDIN per kilogram of body weight daily for two months, along with their meals. CAPRIDIN is a Kondor Pharma (Canada) product that contains medium-chain fatty acids. These compounds are used in ketogenic diets and induce ketogenesis. Ketogenic-based treatments are employed in controlling metabolic-related diseases such as obesity. The intervention group is advised to limit carbohydrate sources in their daily diet. To reduce dietary carbohydrate sources, patients are given general instructions. Given that MASLD does not have a standard treatment and most therapeutic approaches are based on lifestyle changes and weight loss, there are no contraindications for using potential treatments such as cholesterol and triglyceride-lowering medications, according to the treating physician. If patients take these medications, the selection of the intervention and control groups will be equal in terms of medication use

Category
Other

2

Description
Control group: Patients with metabolic-associated fatty liver disease (MASLD) who do not receive any CAPRIDIN-containing regimen. Given that MASLD does not have a standard treatment and most therapeutic approaches are based on lifestyle changes and weight loss, there are no contraindications for the use of potential treatments such as cholesterol and triglyceride-lowering medications, according to the treating physician.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Research Institute for Gastroenterology and Liver Diseases Shahid Beheshti University of Medical Sci

Full name of responsible person
Behzad Hatami

Street address
Ayatollah Taleghani Hospital, Yaman St., Arabi St., Chamran Highway, Volanjak, Tehran

City
Tehran

Province
Tehran

Postal code
1985717413

Phone
+98 21 2243 2519

Email
bzd_hatami@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Saeed Karima

Street address
Department of Clinical Biochemistry, Shahid Behehshti University of Medical Sciences, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 9666 1028

Email
karima@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Behbalin Inc.

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Saeed Karima

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

Street address
Department of Clinical Biochemistry, Shahid Beheshti University of Medical Sciences, Tehran

City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2387 2570
Email
karima@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Behzad Hatami
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Gastroenterology and Hepatology
Street address
Taleghani Hospital, Yaman St., Arabi St., Chamran Highway, Volanjak, Tehran
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2519
Email
bzd_hatami@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sajad Ehtiati
Position
Doctor of Philosophy (Ph.D.) in Clinical Biochemistry
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Department of Clinical Biochemistry, Shahid Beheshti University of Medical Sciences, Tehran
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2387 2570
Email
sajadehtiati@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All study data can be published after the de-identification of subjects.
When the data will become available and for how long
Access begins 1 year after the publication of the results
To whom data/document is available
The data will be made available to academic researchers
Under which criteria data/document could be used
There is no special restriction in this case
From where data/document is obtainable
To receive the data, the request must be sent via email to the person responsible for the project
What processes are involved for a request to access data/document
After the approval of the project manager and colleagues, the data will be provided to the applicant.
Comments