

# 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 science

**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

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#### 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 Beheshti University of Medical Sciences, Tehran, Iran

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1985717443

##### Phone

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##### 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

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## Person responsible for scientific inquiries

### Contact

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Shahid Beheshti University of Medical Sciences  
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Behzad Hatami  
**Position**  
Associate professor  
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Subspecialist  
**Other areas of specialty/work**  
Gastroenterology and Hepatology  
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## 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  
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sajadehtiati@sbm.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