

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Study the effect of metabolic treatment based on a diet containing CAPRIDIN on adenosine regulatory pathways in brain tissue of patients with drug-resistant epilepsy

#### Protocol summary

##### Study aim

Determining the effect of metabolic treatment based on CAPRIDIN consumption on adenosine regulatory pathways in the brain tissue of patients with drug-resistant temporal lobe epilepsy

##### Design

A clinical trial with a control group, with parallel groups, non blinded, randomized, phase 1-2 on 10 patients.

##### Settings and conduct

A number of 10 patients who refer to the Neurological Center of Imam Khomeini Hospital due to refractory temporal lobe epilepsy. After the face-to-face training session, the intervention group consumes a capridin product produced by HealthWeX Company (Canada) for 2 months, fasting consumption daily, at an average of 30 cc. In order to reduce dietary carbohydrate sources, general instructions are given to patients. Non-blind study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 15 to 65 with a history of chronic epilepsy whom neurologists diagnose as candidates for surgery. Exclusion criteria: 1) Any previous consumption of any types of ketogenic diet 2) Metabolic syndrome patients

##### Intervention groups

Patients assigned to the intervention group, in addition to the standard treatment, during the two months before surgery, receive an average of 30 cc of CAPRIDIN daily with food. Patients in the control group received only standard epilepsy treatment during this period.

##### Main outcome variables

Expression level of ecto-5-nucleotidase (CD73) in the patients brain tissue

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170315033086N11**

Registration date: **2023-05-31, 1402/03/10**

Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**

Update count: **0**

##### Registration date

2023-05-31, 1402/03/10

##### 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

2023-06-05, 1402/03/15

##### Expected recruitment end date

2024-06-04, 1403/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Study the effect of metabolic treatment based on a diet containing CAPRIDIN on adenosine regulatory pathways in brain tissue of patients with drug-resistant epilepsy

## Public title

Study the effect of CAPRIDIN in the metabolic treatment of drug-resistant epilepsy

## Purpose

Basic science

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with drug-resistant temporal lobe epilepsy  
Taking up to 3 or more standard anticonvulsants  
Having at least 3 seizures per month.

### Exclusion criteria:

Failure to adhere to dietary guidelines. Metabolic syndrome  
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: **10**

## Randomization (investigator's opinion)

Randomized

## Randomization description

- "Random Allocation V.2" software is used for randomization. This software can be downloaded from the following link:  
<https://random-allocation-software.software.informer.com>  
In this study, one block is used for the randomization. - Patients will be allocated in two intervention and control groups in equal numbers.

## 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 Health S

##### Street address

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

## City

Tehran

## Province

Tehran

## Postal code

1985717434

## Approval date

2023-02-21, 1401/12/02

## Ethics committee reference number

IR.SBMU.MSP.REC.1401.613

## Health conditions studied

### 1

#### Description of health condition studied

Drug-resistant temporal lobe epilepsy

#### ICD-10 code

G40.2

#### ICD-10 code description

Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures

## Primary outcomes

### 1

#### Description

Expression level of ecto-5-nucleotidase (CD73) in the patients brain tissue

#### Timepoint

Two months after taking CAPRIDIN and then brain tissue sampling after surgery.

#### Method of measurement

Using Real-Time PCR and Western blot techniques

### 2

#### Description

Expression level of adenosine kinase in the patients brain tissue

#### Timepoint

Two months after taking CAPRIDIN and then brain tissue sampling after surgery.

#### Method of measurement

Using Real-Time PCR and Western blot techniques

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: patients who take 30 cc of CAPRIDIN daily with food, in addition to the standard treatment of epilepsy, for an average of two months. Capridin is a product of HealthWeX (Canada) that contains medium chain fatty acids. These compounds are used in

ketogenic diets and induce ketogenesis. Treatments based on ketogenesis in the control of epilepsy are among the approved treatments for this disease.

**Category**

N/A

**2****Description**

Control group: patients are receiving only standard epilepsy treatment. Antiepileptic drugs are often used as the first line of treatment and as standard treatment. The most important antiepileptic drugs include phenobarbital, carbamazepine, phenytoin, valproic acid, lamotrigine, and levetiracetam. Depending on the specialist doctor's diagnosis and the individual's clinical conditions, any of these drugs may be prescribed for patients.

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini Hospital Complex

**Full name of responsible person**

Abbas Tafakhori

**Street address**

Keshavarz Blvd. Gharib St. Imam Khomeini Hospital Complex, Tehran, Iran

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**Province**

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1419733141

**Phone**

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**Email**

Imamhospital@tums.ac.ir

**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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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**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Saeed Karima

**Position**

Assistant Professor of Biochemistry

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Abbas Tafakhori

**Position**

Professor of Neurology

**Latest degree**

Specialist

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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**

Seyyed Hossein Khatami

**Position**

Clinical biochemist

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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**Phone**

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**Email**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Collected deidentified IPD, IPD collected for the primary outcome measure only.

**When the data will become available and for how long**

Deidentified data will be available starting from March 2026

**To whom data/document is available**

Who are working in academic institutions or working in nutritional companies. .

**Under which criteria data/document could be used**

No specific condition.

**From where data/document is obtainable**

Saeed Karima (Floor 8, School of Medicine, Shahid Beheshti University of Medical Sciences, Tehran. Iran)  
Email: karima@sbmu.ac.ir

**What processes are involved for a request to access data/document**

The process: 1- Asking a written request contain the main reasons of data importance for the applicant 2- After receiving the request letter, data will be provided within one month.

**Comments**