

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

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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

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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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**

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Position

Professor of Neurology

Latest degree

Specialist

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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