

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Evaluation the effect of probiotic supplementation on clinical symptoms and biochemical indices in children with drug-resistant epilepsy

#### Protocol summary

##### Study aim

Evaluation the effect of probiotic supplementation on clinical symptoms and biochemical indices in children with drug-resistant epilepsy

##### Design

Non-randomized clinical trial without control group

##### Settings and conduct

This study will be done on epileptic children who had been on adequate anticonvulsant medication for more than one year but their seizures was not stopped. First the patient's seizure will be recorded for one month .Then probiotics will be given for two months. Blood parameters and seizure parameters will be compared before and after. The study site will be Shahid Beheshti Hospital in Kashan.

##### Participants/Inclusion and exclusion criteria

Treatment-resistant epileptic patients under the age of 16 with no history of underlying and progressive brain disease.

##### Intervention groups

Resistant epileptic patients receiving probiotic The intervention group is a group of resistant epilepsy patients who receive one capsule of prokid for 2 months as daily and the results are compared before and after.

##### Main outcome variables

Seizure frequency

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170615034549N2**

Registration date: **2020-06-17, 1399/03/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-17, 1399/03/28**

Update count: **0**

##### Registration date

2020-06-17, 1399/03/28

##### Registrant information

###### Name

Mahmoud Salami

###### Name of organization / entity

Kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5562 1157

###### Email address

salami-m@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-27, 1398/08/05

##### Expected recruitment end date

2020-08-22, 1399/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the effect of probiotic supplementation on clinical symptoms and biochemical indices in children with drug-resistant epilepsy

##### Public title

Evaluation the effect of probiotic on drug-resistant epilepsy

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patients with a diagnosis of refractory epilepsy. Patients are between 3 and 15 years old. children who have a medical record with a medical doctor and have been referred to the pediatric neurosurgery clinic of Shahid Beheshti Hospital for treatment. They have had at least one seizure in the past three months.

**Exclusion criteria:**

Children that the cause of their seizures are secondary such as electrolyte imbalances Children with underlying, genetic or progressive brain diseases. Children who have had probiotic use for one month before the study. Children who take antibiotics with any reason for one month before the study. Children who take any immunosuppressant medication with any reason for one month before the study. Children who take any vitamin or mineral supplement except vitamin D

**Age**

From **3 years** old to **15 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Kashan University of Medical Sciences

**Street address**

Physiology Research Center, Institute of Basic Sciences, Kashan University of Medical Sciences, Kashan, I. R. Iran

**City**

Kashan

**Province**

Isfahan

**Postal code**

8715988141

**Approval date**

2019-10-27, 1398/08/05

**Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1398.076

**Health conditions studied**

**1**

**Description of health condition studied**

Drug resistant epilepsy

**ICD-10 code**

G40

**ICD-10 code description**

Epilepsy and recurrent seizure

**Primary outcomes**

**1**

**Description**

Seizure frequency

**Timepoint**

before and after probiotic treatment

**Method of measurement**

asking frequency of seizure frequency

**Secondary outcomes**

**1**

**Description**

blood indices(Sodium- calcium - potassium - magnesium - hepatic enzymes including alkaline phosphatase, AST and ALT- bilirubin - creatinin)

**Timepoint**

before and after

**Method of measurement**

Measurement of venous blood sample

**Intervention groups**

**1**

**Description**

Intervention group: children with Drug resistant epilepsy that are received oral probiotic supplementation as daily with 2 month. The probiotic supplement is Prokid from Gostaresh Milad Farmed Co., which contains beneficial bacteria ,Bifidobacterium lactis, Lactobacillus acidophilus, Bifidobacterium bifidum, Lactobacillus rhamnos with 6×10<sup>9</sup> CFU concentration.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti Hospital of Kashan

**Full name of responsible person**

Dr. Ahmad Talebian

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Ghotb Ravandi Blvd

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

Kashan University of Medical Sciences

**Full name of responsible person**

Deputy of Research- Kashan University of Medical Sciences

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research@kaums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kashan 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

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

Kashan University of Medical Sciences

**Full name of responsible person**

Dr Ahmad Talebian

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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

Kashan University of Medical Sciences

**Full name of responsible person**

Mahmoud Salami

**Position**

professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiology

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**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Fatemeh Zarei

**Position**

MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiology

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**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**

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**

Publishing results as a paper

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

permanently as a paper

**To whom data/document is available**

All people

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

For research and therapeutic aims (if possible)

**From where data/document is obtainable**

Dr. Salami

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

Simply accessibility to the published paper

**Comments**