

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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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

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 6×10⁹ 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Person responsible for updating data

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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