

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### The effect of probiotic supplements in children with drug-resistant epilepsy

#### Protocol summary

##### Study aim

evaluate the effect of probiotics on seizure attacks in children with drug-resistant epilepsy

##### Design

The present quasi-experimental, single-center study was performed on 20 patients with drug-resistant epilepsy.

##### Settings and conduct

Twenty children (1-14 years old) with drug-resistant epilepsy were admitted to the pediatric epilepsy clinic of Ghaem Hospital between 2016-2018. Our sampling was simple. Each child was monitored for two months, during which time the type of seizure, the number of attacks per month, and the duration of each attack were recorded by the parents. After two months, the symbiotic (Kidilact) was mixed and fed with 2 teaspoons of milk or baby food daily and the above variables were re-evaluated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with drug-resistant epilepsy; Treated with anticonvulsant drugs for at least two months before entering the study; At least two seizures in the last week; Informed parental consent to participate in the study. Exclusion criteria: Systemic disorder such as immune deficiency; Heart disease, kidney disease, endocrine diseases, digestive and liver diseases and hereditary metabolic disorders; treatment with probiotics in the 30 days before to the inclusion in the study; participating in anyother epilepsy-related study.

##### Intervention groups

patients began using probiotics daily, One cartridge of Symbiotic was mixed and fed with 1 teaspoonful of milk or baby food daily. One cartridge from Kidilact is produced by a bio-fermentation company, each pack containing 2 symbiotic carcasses and each carcass containing 1 CFU.

##### Main outcome variables

the number of attacks per month, and the duration of each attack

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161230031668N4**

Registration date: **2020-02-03, 1398/11/14**

Registration timing: **retrospective**

Last update: **2020-02-03, 1398/11/14**

Update count: **0**

##### Registration date

2020-02-03, 1398/11/14

##### Registrant information

##### Name

farah ashrafzadeh

##### Name of organization / entity

Mashhad University of Medical Seinces

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3842 4834

##### Email address

ashrafzadehf@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-03-20, 1395/01/01

##### Expected recruitment end date

2019-05-22, 1398/03/01

##### Actual recruitment start date

2016-03-20, 1395/01/01

##### Actual recruitment end date

2019-02-20, 1397/12/01

##### Trial completion date

2019-06-22, 1398/04/01

## Scientific title

The effect of probiotic supplements in children with drug-resistant epilepsy

## Public title

effect of probiotic supplements on epilepsy

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with drug-resistant epilepsy Treated with anticonvulsant drugs for at least two months before entering the study At least two seizures in the last week Informed parental consent to participate in the study

### Exclusion criteria:

Systemic disorder such as immune deficiency Heart disease, kidney disease, endocrine diseases, digestive and liver diseases and hereditary metabolic disorders treatment with probiotics in the 30 days before to the inclusion in the study participating in anyother epilepsy-related study

## Age

To **14 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **20**

Actual sample size reached: **20**

## Randomization (investigator's opinion)

Randomized

## Randomization description

simple randomization,A list of patients who met the inclusion criteria prepared and 20 patients was selected using a random number table.

## 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

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Building Ghosheshi, Central Organization of Mashhad University of Medical Sciences, Daneshgah Avenue,

Mashhad, Iran.

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

1394491388

#### Approval date

2019-06-13, 1398/03/23

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.510

## Health conditions studied

### 1

#### Description of health condition studied

epilepsy

#### ICD-10 code

G40

#### ICD-10 code description

Epilepsy and recurrent seizures

## Primary outcomes

### 1

#### Description

the number of attacks per month

#### Timepoint

Every week for a month

#### Method of measurement

Parental report

### 2

#### Description

the duration of each attack

#### Timepoint

Every week for a month

#### Method of measurement

Parental report

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: patients with drug-resistant epilepsy began using probiotics daily, one cartridge of Symbiotic was mixed and fed with 1 teaspoonful of milk or baby food daily for one month. One cartridge from Kidilact is produced by a bio-fermentation company, each pack containing 15 symbiotic cartridges. Usual consumption is 1-2 cartridges per day.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Dr Farah Ashrafzadeh

**Street address**

Ghaem Hospital, Shariati Square, Ahmad Abad Street, Mashhad, Iran.

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**Email**

ashrafzadehf@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

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tafaghodim@mums.ac.ir

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Farah Ashrafzadeh

**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**

Mashhad University of Medical Sciences

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Farah Ashrafzadeh

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mozhgan Heidari

**Position**

resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

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**Email**

HeidariMZ951@mums.ac.ir

## Sharing plan

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

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available