Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Ghoreshi, 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.

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3841 2324

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

Street address
Building Ghoreshi, Central Organization of Mashhad University of Medical Sciences, Daneshgah Avenue, Mashhad, Iran.

City
Mashhad

Province
Razavi Khorasan

Postal code
1394491388

Phone
+98 51 3841 2081

Email
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

Street address
Ghaem Hospital, Shariati square,Ahmad Abad Street, Mashhad, Iran.

City
Mashhad

Province
Razavi Khorasan

Postal code
9838417403

Phone
+98 51 3842 2324

Email
ashrafzadehf@mums.ac.ir

Person responsible for scientific 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

Street address
Neurology department of Ghaem hospital, Shariati Square, Ahmad Abad Street, Mashhad, Iran.

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3852 5209

Fax

Email
ashrafzadehf@mums.ac.ir

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

Street address
Ghaem Hospital, Shariati square,Ahmad Abad Street, Mashhad, Iran.

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Phone
+98 51 3441 2324

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