

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of probiotics effect on quality of life and seizure attacks in patients with refractory epilepsy in pediatric neurology clinics of Urmia University of Medical Sciences

Protocol summary

Study aim

Determining the effect of Reuteflor probiotic on the quality of life and reduction of seizures in treatment-resistant epilepsy patients in pediatric neurology clinics of Urmia University of Medical Sciences.

Design

The samples under investigation in the present study are 75 children with epilepsy resistant to treatment with an age range of 3 to 18 years old that referred to pediatric clinics of Urmia University of Medical Sciences, who were selected consecutively and available according to the inclusion criteria

Settings and conduct

The present study is an intervention study of before and after type. The place of study is pediatric neurology clinics of Urmia University of Medical Sciences

Participants/Inclusion and exclusion criteria

The criteria for inclusion in the study were all drug-resistant epilepsy patients between the ages of 3 and 18 year old. Exclusion criteria : the development of serious complications following the use of drugs, lack of satisfaction with the continuation of the study, Non-epileptic seizures, change in the dose and type of anti-epileptic drugs in the last 30 days, probiotic consumption in the last 30 days, insufficiency Renal or hepatic, lactose intolerance, celiac disease, long-term antibiotic use and life expectancy of less than 1 year, as well as the presence of progressive neurodegenerative disease, the presence of any psychiatric disorder, and the receipt of relevant drugs according to the parents' opinion.

Intervention groups

In the present study, the intervention is the prescription of probiotic medicine. The probiotic under investigation, is Reuteflor that contains lyophilized lactobacillus reuteri bacteria with a daily dose of one sachet will be given.

Main outcome variables

The average number of convulsions of patients with

resistant epilepsy 3 months after the start of probiotic and before the start of the intervention is different.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221024056286N1**

Registration date: **2022-12-21, 1401/09/30**

Registration timing: **prospective**

Last update: **2022-12-21, 1401/09/30**

Update count: **0**

Registration date

2022-12-21, 1401/09/30

Registrant information

Name

Parisa Alaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3343 8795

Email address

hamed.nodet@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of probiotics effect on quality of life and seizure attacks in patients with refractory epilepsy in pediatric neurology clinics of Urmia University of Medical Sciences

Public title
Evaluation of probiotics effect on quality of life and seizure attacks in patients with refractory epilepsy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
patients with refractory epilepsy
Exclusion criteria:
Cause serious complications following drug use
Dissatisfaction with continuing the study
Non-epileptic seizures
History of status epilepticus in the last 12 months
Change in dose and type of antiepileptic drugs in the last 30 days
Probiotic consumption in the last 30 days
Chronic GI diseases, kidney or liver failure
lactose intolerance
Life expectancy less than 1 year
Presence of progressive neurodegenerative disease
Presence of any psychiatric disorder

Age
From **3 years** old to **18 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **75**

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
Ethics committee of Urmia University of Medical Sciences

Street address
no 10 . 37 ave Beheshti blv

City
Urmia

Province
West Azarbaijan

Postal code
5715844331

Approval date
2021-08-11, 1400/05/20

Ethics committee reference number
IR.UMSU.REC.1400.195

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
Quality of life score in Quality of Life in Childhood Epilepsy Questionnaire version 55

Timepoint
3 months before and 3 month later

Method of measurement
Quality of life score in Quality of Life in Childhood Epilepsy Questionnaire version 55

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Administration of Reuteflor probiotic which contains 300 miligram lyophilized live friendly bacteria , Lactobacillus reuteri , once per day dose that dissolve in cool water or food . it manufactured in Fara Daru company .

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahari Hospital

Full name of responsible person

Parisa Alaie

Street address

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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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

Oroumia University of Medical Sciences

Full name of responsible person

Ghazavi Ahad

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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

Oroumia 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**

Oroumia University of Medical Sciences

Full name of responsible person

Parisa Alaie

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

Oroumia University of Medical Sciences

Full name of responsible person

Parisa Alaie

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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

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Resident

Latest degree

Specialist

Other areas of specialty/work

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After Unrecognize the patients , age , sex , seizure type , Cerebral palsy , seizure frequency , drugs and quality of life will share.

When the data will become available and for how long

sharing will begin 6 month after result printing

To whom data/document is available

expose to all

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Parisa Alaie , Call 00989149773819

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

There is no special process and it will be accessed in the shortest time

Comments