Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

etermining 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
Motahari Hospital , Kashani Ave
City
Urmia
Province
West Azarbaijan
Postal code
5714755241
Phone
+98 44 3223 7077
Email
motahari-h-urm@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Ghazavi Ahad
Street address
Urgency Ave , Resalat ST
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3223 4897
Email
umsu@umsu.ac.ir
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
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
Street address
No 1 , 37th Ave , Beheshti Blvd
City
Urmia
Province
West Azarbaijan
Postal code
5715822334
Phone
+98 44 3343 8795
Email
hamed.nodet@gmail.com

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
Street address
10 Apartment No 1 37 Ave Shahid beheshti st.
City
Urmia
Province
West Azarbaijan
Postal code
5715833443
Phone
+98 44 3343 8795
Fax
Email
Hamed.nodet@gnail.com

Person responsible for updating data

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
Street address
10 Apartment No 1 37 Ave Shahid beheshti st.

City
Urmia
Province
West Azarbaijan
Postal code
5715833443
Phone
+98 44 3343 8795
Fax
Email
Hamed.nodet@gnail.com

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