

# 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**

Motahari Hospital , Kashani Ave

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714755241

**Phone**

+98 44 3223 7077

**Email**

motahari-h-urm@umsu.ac.ir

**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

**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

**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@gmail.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

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10 Apartment No 1 37 Ave Shahid beheshti st.

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**Fax****Email**

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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**