

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of synbiotics on children with drug-resistant epilepsy in children referred to the clinics of Arak University of Medical Sciences and the quality of life of their caregivers

Protocol summary

Study aim

Determining the effect of synbiotic supplementation on the number of epileptic seizures in children with refractory epilepsy and the quality of life of caregivers

Design

This before and after clinical trial was performed on 30 children with refractory seizures. We do not have blindness in this study and the study will be done Open-Labelled. The effect of synbiotics in a group will be examined before and after, so randomization is not and will not be done.

Settings and conduct

This before and after clinical trial will be performed on 30 children with refractory seizures referred to the clinics of Arak University of Medical Sciences in 2021, which has been diagnosed by a pediatric neurologist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age group 1 year to 15 years old; having at least one seizure per month despite the use of anticonvulsant drugs in the last three months; no history of hypertension; no active infection; no history of gastrointestinal ulcers; minimal consumption Anticonvulsant drug as a single drug with appropriate amount and duration (at least 2 months) and lack of seizure control. Exclusion criteria: infants with infantile spasm; recent history of false seizures; active infection; history of hypertension; history of gastrointestinal tract ulcers; patients who terminate the treatment plan earlier than scheduled due to personal reasons and lack of necessary cooperation and communication.

Intervention groups

For previous anticonvulsant medications, the infant should use paddy lactate at a dose of 5 to 15 drops per day for 8 weeks daily, and children 2 to 15 years old should take Kidi lactate at a dose of 1 sachet per day for 8 weeks daily for up to one month.

Main outcome variables

Number of epileptic seizures; quality of life caregivers; seizure onset time; aura

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200519047517N1**

Registration date: **2021-10-11, 1400/07/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-11, 1400/07/19**

Update count: **0**

Registration date

2021-10-11, 1400/07/19

Registrant information

Name

amirali mottaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3464

Email address

md.mottaghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of synbiotics on children with drug-resistant epilepsy in children referred to the clinics of Arak University of Medical Sciences and the quality of life of their caregivers

Public title
Evaluation of the effect of probiotics in resistant pediatric epilepsy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 1 year to 15 years Having at least one seizure a month despite using anticonvulsants for the past three months Taking at least 3 anticonvulsant drugs as a single drug with appropriate amount and duration (at least 2 months) and lack of seizure control No history of hypertension Absence of active infection No history of gastrointestinal ulcers
Exclusion criteria:
Infants with infantile spasm Recent history of pseudo-seizures Active infection History of hypertension History of gastrointestinal ulcers in patients Patients who terminated the treatment plan earlier than scheduled due to personal reasons, lack of necessary cooperation and communication.

Age
From **1 year** old to **15 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

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

Research Ethics Committees of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Sardasht

City

Arak

Province

Markazi

Postal code

3848176589

Approval date

2021-06-27, 1400/04/06

Ethics committee reference number

IR.ARAKMU.REC.1400.077

Health conditions studied

1

Description of health condition studied

Resistant epilepsy

ICD-10 code

G40.1

ICD-10 code description

Other generalized epilepsy and epileptic syndromes, not intractable, with status epilepticus

Primary outcomes

1

Description

Number of epileptic seizures per month

Timepoint

One Month

Method of measurement

The ZARIT burden questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

To previous anticonvulsant drugs, the infant patient should use Pedi Lactic 5 to 15 drops per day for 8 weeks daily and children 2 to 15 years old should take Kidi Lactic 1 sachet per day for 8 weeks daily for up to one month. synbiotics will be used by Bio Fermentation Company made in Iran.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Amirali Mottaghi

Street address

Alamolhoda Blvd., Arak Town

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3819693345

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elamirali313@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr. Aalireza Kamali

Street address

Arak University of Medical Sciences, Sardasht Ave.

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amozesh@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Fakhreddin Shariatmadari

Position

Associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fakhreddin Shariatmadari

Position

associated professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fakhredin Shariatmadari

Position

associated professor

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

After identifying people, it is shared

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

researchers

Under which criteria data/document could be used

Citation of data is unrestricted

From where data/document is obtainable

Email responsible for the plan

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

After checking the accuracy of the information in the applicant

Comments