

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of co-amoxiclav on seizure frequency in drug-resistant epilepsy in children

Protocol summary

Study aim

Determining the effect of coamoxiclav drug on the frequency of seizures in children with drug-resistant epilepsy

Design

A controlled, unblinded, phase 2 clinical trial on 20 patients

Settings and conduct

This study was designed as a non-blind clinical trial on children with drug-resistant epilepsy referred to the clinic of Bo Ali Sina Hospital in Sari in 2022. In this study, the first stool sample is taken from 20 patients after the initial interview. And the second stool sample is taken after a 5-day period of Amoxiclav drug consumption, 5-7 days apart from the first sample. Also, 9 healthy children are sampled once. Stool samples are collected and stored in special containers in a freezer at -20 until specialized tests are performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 3-18 years who had an established diagnosis of drug-resistant epilepsy, and had two or more seizures during a week. Consent of the patient or his/her guardian. The exclusion criteria: History of penicillin allergy, patients treated with co-amoxiclav interfering drugs, reception of corticosteroids, taking antibiotics in the last 1 month or needing to take another antibiotic during the study period, liver disease, patients who are candidates for epilepsy surgery or other non-pharmacological methods, and need to change the dose of anticonvulsant during the study period.

Intervention groups

In this study, the first stool sample was taken from 20 patients. And the second stool sample was taken after a 5-day period of taking Amoxiclav, 5-7 days apart from the first sample. Also, 9 healthy children were sampled once.

Main outcome variables

Evaluating the frequency of seizures in patients with drug-resistant epilepsy before and after receiving

coamoxiclav, investigating changes in intestinal microbes in patients with drug-resistant epilepsy before and after receiving coamoxiclav

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090412001808N8**

Registration date: **2024-01-29, 1402/11/09**

Registration timing: **retrospective**

Last update: **2024-01-29, 1402/11/09**

Update count: **0**

Registration date

2024-01-29, 1402/11/09

Registrant information

Name

Ali Abbaskhanian

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1223 3010

Email address

aabbaskhanian@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

2022-06-25, 1401/04/04

Actual recruitment end date

2023-09-22, 1402/06/31

Trial completion date

2023-09-22, 1402/06/31

Scientific title

Evaluation of co-amoxiclav on seizure frequency in drug-resistant epilepsy in children

Public title

Evaluation of co-amoxiclav on seizure frequency in drug-resistant epilepsy in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children aged 3-18 years An established diagnosis of drug-resistant epilepsy with two or more seizures during the 7-day baseline period Consent of the patient or the patient's guardian to participate in the study

Exclusion criteria:

History of penicillin allergy Patients treated with co-amoxiclav interfering drugs reception of corticosteroids Taking antibiotics in the last 1 month or needing to take another antibiotic during the study period Liver disease Patients who were candidates for epilepsy surgery or other non-pharmacological methods Patients who need to change the dose of anticonvulsant during the study period

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **25**

Actual sample size reached: **20**

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 the Mazandaran University of Medical Sciences

Street address

Research and Technology Deputy Building., Moalem Square

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Approval date

2020-06-21, 1399/04/01

Ethics committee reference number

IR.MAZUMS.REC.1399.5208

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 primary laboratory outcome is defined as changes in the microbial load of different species in stool samples on the fifth day compared to baseline.

Timepoint

The first stool sample is taken from patients after the initial interview. The second stool sample is taken after 5 days of taking co-amoxiclav, 5-7 days apart from the first sample.

Method of measurement

Bacterial copy number is determined in patients' feces samples using real-time PCR technique.

2**Description**

The primary clinical outcome is response rate at week 12. A response rate of $\geq 50\%$ reduction in seizures is classified as "responder" and less than 50% reduction in seizure frequency is classified as "non-responder".

Timepoint

The patient and his/her family are asked to record the frequency of seizures up to 12 weeks after receiving the drug.

Method of measurement

Self report

Secondary outcomes

empty

Intervention groups

1

Description

Administer coamoxiclav at a dose of 40 mg/kg/d in two divided doses for 5 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Boo'Ali Sina Hospital

Full name of responsible person

Ali Abaskhanian

Street address

Boo'Ali Sina Hospital, Pasdaran Blvd

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۸۳۸۴۷۷

Phone

+98 11 3334 3010

Fax

Email

aabbaskhanian@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ali Abaskhanian

Street address

Mazandaran University of Medical Sciences, Valie-Asr Boulevard, Sari, Mazandaran

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3304 4000

Email

info@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Ali Abaskhanian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

Street address

Boo'Ali Sina Hospital, Pasdaran Blvd

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۸۳۸۴۷۷

Phone

+98 11 3334 3010

Email

aabbaskhanian@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ali Abaskhanian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Neurology

Street address

Boo'Ali Sina Hospital., Pasdaran Blvd

City

Sari

Province

Mazandaran

Postal code

۴۸۱۵۸۳۸۴۷۷

Phone

+98 11 3334 3010

Email
aabbaskhanian@mazums.ac.ir

azadehsheidaee@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Kobra Sheidaee
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Neurology
Street address
Boo'Ali Sina Hospital., Pasdaran Blvd
City
Sari
Province
Mazandaran
Postal code
۴۸۱۵۸۳۸۴۷۷
Phone
+98 11 3334 3010
Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available