

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The efficacy of treatment with 5 days methylprednisolone pals on electroencephalography in children with refractory epilepsy .

Protocol summary

Study aim

Determination of the efficacy of pulse methylprednisolone on electroencephalography findings in children refractory epilepsy

Design

A single, unblinded, unrandomized, phase 2 clinical trial of 50 patients

Settings and conduct

Children with refractory epilepsy who refer to the children's neurology clinic of Shahada Tajrish and Mofid hospitals and EEG is taken from them while asleep or awake, written consent is obtained, and then Children are admitted to the neurology department. As soon as the patient is hospitalized, routine laboratory tests are taken from the patient. and if there are no infectious issues and other exclusions, with a dose of 20 mg/kg of body weight for 5 consecutive days, intravenous methylprednisolone with monitoring vital signs and recording it while receiving the drug; It is injected regularly.

Participants/Inclusion and exclusion criteria

Conditions for entering the study included children who based on history and physical examination and electroencephalogram have epilepsy syndromes such as Infantile spasm, Landau-Kleffner syndrome, seizure disorders with waves like hypsarrythmia or burst suppression pattern Exclusion conditions included fever, leukocytosis, high ESR and CRP, positivity of blood culture, positivity of covid PCR test, unknown metabolic disorders, positive ppd test, age under 2 months, age over 15 years and cases where corticosteroid use is contraindicated.

Intervention groups

Children with refractory epilepsy treated with a 5-days methylprednisolon period.

Main outcome variables

Electroencephalography ; Type of seizure ; Control of seizure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240615062138N1**

Registration date: **2025-03-02, 1403/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2025-03-02, 1403/12/12**

Update count: **0**

Registration date

2025-03-02, 1403/12/12

Registrant information

Name

Khatereh Bagheramiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 911 210 6334

Email address

khatereh.bagheramiri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2025-03-21, 1404/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of treatment with 5 days methylprednisolone pulse on electroencephalography in children with refractory epilepsy .

Public title

Effect of methylprednisolone pulse in treatment of children with refractory epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children who based on history and physical examination and electroencephalogram have epilepsy syndromes such as Infantile spasm, Landau-Kleffner syndrome, seizure disorders with waves like hypsarrhythmia or burst suppression pattern

Exclusion criteria:

Fever leukocytosis high ESR and CRP positivity of blood culture positivity of covid PCR test unknown metabolic disorders positive PPD test, age under 2 months or age over 15 years cases where corticosteroid use is contraindicated

Age

From **3 months** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences and Healthcare Services, Arabi street, Yemen street, Tehran city.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2024-05-27, 1403/03/07

Ethics committee reference number

IR.SBMU.MSP.REC.1403.096

Health conditions studied

1

Description of health condition studied

Refractory epilepsy

ICD-10 code

G40.919

ICD-10 code description

Epilepsy, unspecified, intractable, without status epilepticus

Primary outcomes

1

Description

The changes and improvement of EEG before and after receiving methylprednisolone pulse

Timepoint

before the start of the intervention and one day after receiving the intervention and 6, 12, 18, 24 months after the intervention

Method of measurement

Questionnaire and reading and comparison of EEGs by a specialist in pediatric neurology and a specialist in pediatric neurology and electrophysiology and epilepsy fellowship.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This intervention is conducted in patients based on the history and clinical examination of seizures and confirmed in the ideal state of the brain EEG. The method of working is that by diagnosing patients who refer to the Children's Neuroscience Clinic of Shohadaye Tajrish and Mofid Hospitals (based on the include and exclude criteria of the study) and in the sleep or wake of EEG, they obtain a written consent. They are then hospitalized in the neurological section of the children. As soon as the routine tests are hospitalized, infectious examination and electrolytes and kidney function are taken from the patient and if they do not have infectious issues and other exclusion at a dose of 20 mg / kg body weight methylprednisolone for 5 consecutive days in a row with vital symptoms and

symptoms. Registration is injected regularly during the medication. Evaluated during hospitalization and third day. One day after receiving the last dose of the day, the EEG will be taken again in sleep or wake up. The patient will be discharged by age and gender after general recovery and seizures) in a number of anti -epithelials related to the type of seizures (and will be followed for 2 years in 6, 12,18 and 24 followed up. Clinical symptoms and seizures control, drug complications and EEG findings will be investigated.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children Hospital and Shohadaye Tajrish Hospital

Full name of responsible person

Khatereh Bagheramiri

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No.28, Haftlang street, Southeast Adl street, Punak, Tehran city.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Ali Ziae

Street address

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

50

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khatereh Bagheramiri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Position

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

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

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

Information about the main outcome and the percentage of improvement of EEGs can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Physicians and researchers in the field of neurology, especially children's epilepsy

Under which criteria data/document could be used

Research on the same topic and on the treatment of various refractory epilepsy syndromes in children. If using the research data, do not compare with another control group. In case of using the data and their analysis in the new research, the name of the research must be mentioned in the sources and text.

From where data/document is obtainable

via SMS to the number 09112106334 in the name of Khatereh Bagheramiri Or email to khatereh.bagheramiri@gamil.com

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

Detailed information of the applicant including name and surname, national number, medical system number, name of the university and research center, mobile number and email address, the subject of research and the method of conducting the research and the purpose of the research should be mentioned in the application.

Comments