Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Public title
Effect of methylprednisolone pals 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 hypsarrythmia 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 methylprednisolon 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

Street address
No.28, Haftlang street, Southest 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
No.28 , Haftlang st., Southest Adl st., Punak,Tehran city

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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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Name of organization / entity
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Position
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Person responsible for updating data

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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 Baghramiri 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