

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of clinical efficacy and safety of injectable Levetiracetam versus Phenytoin as second line drug in the management of generalized convulsive status epilepticus in children: An open label randomized control trial

Protocol summary

Study aim

To compare the clinical efficacy and safety of injectable Levetiracetam versus Phenytoin as a second-line drug in the management of generalized convulsive status epilepticus in children.

Design

Parallel open-label randomized control trial.

Settings and conduct

Emergency department, Children's Hospital and the Institute of Child Health, Multan, Pakistan

Participants/Inclusion and exclusion criteria

Male and Female Patients aged one to 14 years. Patients with generalized convulsive status epilepticus, not responding to two doses of diazepam (0.2 mg/kg) given 5 minutes apart. Parents /guardians of children willing to give Written informed consent. Children received anticonvulsant treatment other than benzodiazepine for the acute management of CSE. Children on assisted ventilation. Children with CSE secondary to hypertensive encephalopathy, head injury, chronic kidney or liver disease and electrolyte derangement (hypoglycemia, hypocalcemia, hypo/hyponatremia, hypomagnesemia)

Intervention groups

Group A: Levetiracetam 40mg/kg infused in 15 minutes
Group B: Phenytoin 20 mg/kg infused in 30minutes.

Main outcome variables

Efficacy: cessation of seizures within 30 minutes of administration. Safety: • Respiratory depression • Cardiac depression • Hypotension • Central nervous system (CNS) depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170614034526N2**

Registration date: **2018-09-26, 1397/07/04**

Registration timing: **retrospective**

Last update: **2018-09-26, 1397/07/04**

Update count: **0**

Registration date

2018-09-26, 1397/07/04

Registrant information

Name

Dr. Sharib Syed Muhammad

Name of organization / entity

Hilton Pharma Pvt Ltd

Country

Pakistan

Phone

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sharibsyed@hiltonpharma.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-01-27, 1392/11/07

Expected recruitment end date

2018-05-30, 1397/03/09

Actual recruitment start date

2014-01-30, 1392/11/10

Actual recruitment end date

2018-06-20, 1397/03/30

Trial completion date

2018-06-30, 1397/04/09

Scientific title

Comparison of clinical efficacy and safety of injectable

Levetiracetam versus Phenytoin as second line drug in the management of generalized convulsive status epilepticus in children: An open label randomized control trial

Public title

Comparison of clinical efficacy and safety of injectable Levetiracetam versus Phenytoin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male and Female Patients aged one to 14 years. Patients with generalized convulsive status epilepticus, not responding to two doses of diazepam (0.2 mg/kg) given 5 minutes apart. Parents /guardians of children willing to give Written informed consent.

Exclusion criteria:

Children received anticonvulsant treatment other than benzodiazepine for the acute management of CSE. Children on assisted ventilation Children with CSE secondary to hypertensive encephalopathy, head injury, chronic kidney or liver disease and electrolyte derangement (hypoglycemia, hypocalcaemia, hypo/hyponatremia, hypomagnesaemia)

Age

From **1 year** old to **14 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **650**

Actual sample size reached: **600**

Randomization (investigator's opinion)

Randomized

Randomization description

Children were divided into two groups by random allocation for the selection of second-line drug. Children received Levetiracetam were assigned as group A (LEV group) and those received phenytoins were assigned as group B (PHT group). Sealed envelope system was used for randomization. A set of envelopes were prepared, each bearing the name of the drug (Phenytoin and Levetiracetam were written on 300 envelopes each) on it. All envelopes were sealed properly and shuffled by a person not involved in the study. These pre-written, drug named sealed envelopes were opened at the time of administration of the second-line drug for the management of CSE.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Children Hospital and institute of Child Health, Multan.

Street address

Sher Shah Rd, Nawa Shehar, Mohalla Qadirabad,

City

Multan

Postal code

60000

Approval date

2014-01-25, 1392/11/05

Ethics committee reference number

CHICH/EC/DR.NUZHAT NOUREEN/25-01-2014/109

Health conditions studied

1

Description of health condition studied

Generalized convulsive status epileptics.

ICD-10 code

G41.8

ICD-10 code description

Other status epilepticus

Primary outcomes

1

Description

Efficacy: cessation of seizures

Timepoint

within 30 minutes of administration

Method of measurement

Visual Inspection

Secondary outcomes

1

Description

Safety: • Respiratory depression • Cardiac depression • Hypotension • Central nervous system (CNS) depression

Timepoint

From administration of study drug till the patient under monitoring for acute condition.

Method of measurement

Monitoring was done by base line arterial blood gases, electrocardiogram, blood pressure and Glasgow coma scale.

Intervention groups

1

Description

Intervention group: Group A: Levetiracetam 40mg/kg infused in 15 minutes

Category

Treatment - Drugs

2

Description

Control group: Group B: Phenytoin 20 mg/kg infused in 30minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Hospital and institute of Child Health

Full name of responsible person

Dr. Nuzhat Noureen

Street address

Sher Shah Rd, Nawa Shehar, Mohalla Qadirabad,

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Phone

+92 61 9201431

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drnuzhatrana@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Children Hospital and institute of Child Health

Full name of responsible person

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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

Children Hospital and institute of Child Health

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

Children Hospital and institute of Child Health

Full name of responsible person

Dr. Nuzhat Noureen

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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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

To keep the confidentiality of the study participants, however, data would be made available to the Ethics Committee of the institute upon requirement

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available