Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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/hypernatremia, 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
(021) 111-123-000 Ext:428

Email address
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/hypernatremia, 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 envelops 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,
City
Multan
Postal code
60000
Phone
+92 61 9201431
Email
drnuzhatrana@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Children Hospital and institute of Child Health
Full name of responsible person
Dr. Nuzhat Noureen
Street address
Sher Shah Rd, Nawa Shehar, Mohalla Qadirabad,
City
Multan
Postal code
60000
Phone
+92 61 9201431
Email
drnuzhatrana@gmail.com
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
Street address
Sher Shah Rd, Nawa Shehar, Mohalla Qadirabad,
City
Multan
Province
Punjab
Postal code
60000
Phone
+92 61 9201431
Email
drnuzhatrana@gmail.com

Person responsible for scientific 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
Street address
Sher Shah Rd, Nawa Shehar, Mohalla Qadirabad,
City
Multan
Province
Punjab
Postal code
60000

Phone
+92 61 9201431
Email
drnuzhatrana@gmail.com

Person responsible for updating data

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
Street address
Sher Shah Rd, Nawa Shehar, Mohalla Qadirabad,
City
Multan
Province
Punjab
Postal code
60000
Phone
+92 61 9201431
Email
drnuzhatrana@gmail.com

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