Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of efficacy and safety of corticosteroids and vigabatrin plus corticosteroids in infantile spasm: An open label randomized control trial

Protocol summary

Study aim

To identify the optimized treatment of infantile spasm in infants.

Design

Open label randomized control trial will be conducted at neurology department of the Children's Hospital and the Institute of Child Health Multan, Pakistan

Settings and conduct

This open label randomized control trial will be conducted at neurology department of the Children's Hospital and the Institute of Child Health Multan, Pakistan from November 2020 to October 2023. Total 320 infants (160 each group) will be included in this study. The study was approved by the ethical committee of Children Hospital and institute of Child Health, Multan.

Participants/Inclusion and exclusion criteria

Written informed consent Children aged one to 12 months, of both genders clinical diagnosis of infantile spasm made according to international league against epilepsy plus hypsarrhythmia on EEG (EEG records were graded using the Burden of Amplitudes and Epileptiform Discharges (BASED) scoring system) will be included. Exclusion criteria will be: Infantile spasm due to tuberous sclerosis, previous treatment with steroids or vigabatrin, contraindication to steroids/vigabatrin

Intervention groups

Children will be divided into two groups by random allocation for the selection of treatment protocol. Children receiving prednisolone will be assigned as group A and those receiving vigabatrin plus prednisolone as group B. Sealed opaque envelope system will be used for randomization. These pre- written, sealed envelopes will be opened at the time of start of treatment.

Main outcome variables

Primary end point will be the electroclinical remission (cessation of spasms plus resolution of hypsarrhythmia). Resolution of hypsarrhythmia will be defined as BASED score ≤ 2 at day 14. Secondary end points will be the time to electroclinical remission, relapse after initial response, adverse effects of treatment and developmental progress.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200414047072N2**
Registration date: **2020-11-06, 1399/08/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-06, 1399/08/16**
Update count: **0**

Registration date

2020-11-06, 1399/08/16

Registrant information

Name
Saba Fatima
Name of organization / entity
Hilton Pharma Pvt. Ltd.
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Pakistan
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-10, 1399/05/20

Expected recruitment end date

2021-08-10, 1400/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of corticosteroids and vigabatrin plus corticosteroids in infantile spasm: An open label randomized control trial

Public title

Efficacy and Safety of corticosteroids and vigabatrin plus corticosteroids in infantile spasm

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Signed informed consent from parents/guardians Children aged one to 12 months Both genders with clinical diagnosis of infantile spasm made according to international league against epilepsy plus hypsarrhythmia on EEG (EEG records were graded using the Burden of Amplitudes and Epileptiform Discharges (BASED) scoring system

Exclusion criteria:

Infantile spasm due to tuberous sclerosis Previous treatment with steroids or vigabatrin Contraindication to steroids/vigabatrin (fever, active infection and hypertension).

Age

From **1 month** old to **12 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **320**

Randomization (investigator's opinion)

Randomized

Randomization description

Its an open label randomized control trial design and Simple random sampling was occurred, where one group is taken single medicine while other group is taking medicine in combination. Individual unit of randomization where choose Total 320 infants (160 each group), according to international league against epilepsy plus hypsarrhythmia on EEG (EEG records were graded using the Burden of Amplitudes and Epileptiform Discharges (BASED) scoring system) will be included. Sealed opaque envelope system will be used for randomization. These pre- written, sealed envelopes will be opened at the time of start of treatment. real time physical random sequence will be done.

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

The Children's Hospital & the Institute of Child Health, Multan.

Street address

Ab'dali Road, Chowk Fawara, Mohalla Qadirabad, Multan, Punjab

City

Karachi

Postal code

60000

Approval date

2020-08-27, 1399/06/06

Ethics committee reference number

PMD-761/CHC

Health conditions studied

1

Description of health condition studied

Infantile spasm

ICD-10 code

G40.822

ICD-10 code description

Epileptic spasms, not intractable, without status epilepticus

Primary outcomes

1

Description

Electroclinical remission (cessation of spasms plus resolution ofhypsarrhythmia)

Timepoint

Before intervention and Day 4, 7, 14, 21, 28, 42, 60, 90, 120, 150 and day 180

Method of measurement

Fundoscopy and blood pressure

2

Description

EEG will be performed at day 0, 14, 42, 60, 90 and 180. Sleep EEG will be recorded for a minimum duration of 30 minutes according to international 10-20 system of electrode placement.

Timepoint

day 0, 14, 42, 60, 90 and 180

Method of measurement

Burden of Amplitudes and Epileptiform Discharges (BASED) scoring system

3

Description
Developmental assessment
Timepoint
day 0, 90 and 180
Method of measurement
portage early education program (PEEP)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Children will be divided into two groups by random allocation for the selection of treatment protocol. Group A children will receive prednisolone 40 mg/day in 4 divided doses along with an antacid, increased to 60 mg/day at day 8, if spasm present. Symptomatic and supportive treatment will be provided simultaneously to both groups. All children will be physically followed at day 4, 7, 14, 21, 28, 42, 60, 90,120, 150 and 180 for efficacy and adverse drug reactions. Parents/ caregivers will be trained to maintain and complete a seizure diary including the detail of spasms (number, duration of spasm).
Category
Other

2

Description
Intervention group 2: Group B children will receive vigabatrin plus prednisolone (same protocol as of group A). Vigabatrin will be started with 50 mg/kg/day on day 1 increased to 100 mg/kg/day in two divided doses on day 2 for next three days followed by further increment to 150 mg/kg/day on day 5, if still spasm present. Symptomatic and supportive treatment will be provided simultaneously to both groups. All children will be physically followed at day 4, 7, 14, 21, 28, 42, 60, 90,120, 150 and 180 for efficacy and adverse drug reactions. Parents/ caregivers will be trained to maintain and complete a seizure diary including the detail of spasms (number, duration of spasm). They will also advised and trained to record any event that might be adverse reactions of vigabatrin or prednisolone.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The Children's Hospital & the Institute of Child Health, Multan.
Full name of responsible person
Dr. Nuzhat Noureen
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Research Grant
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The Children's Hospital & the Institute of Child Health, Multan.
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

Person responsible for general inquiries

Contact
Name of organization / entity
The Children's Hospital & the Institute of Child Health, Multan.
Full name of responsible person
Dr. Nuzhat Noureen

Position
Associate Professor
Latest degree
Specialist
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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
No - There is not 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
Not applicable
Data Dictionary
Not applicable