# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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.

**Country**

Pakistan

**Phone**

+92 21 35072224

**Email address**

sabafatima@hiltonpharma.com

**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**
Ab'dali Road, Chowk Fawara, Mohalla Qadirabad, Multan, Punjab
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**Phone**
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drnuzhatrana@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
The Children's Hospital & the Institute of Child Health, Multan.
**Full name of responsible person**
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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
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Specialist
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**
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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**
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