Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Comparison of Levetiracetam and Piracetam efficacy on severe Breath Holding Spells; A Randomized Controlled clinical trial

Protocol summary

Study aim
Comparison of the effect of levetiracetam and piracetam on the treatment of severe breath holding spells in children aged 6 months to 6 years in 2019

Design
Randomized, non-blinded, controlled clinical trial with parallel groups

Settings and conduct
This study starts in the winter of 1397 by selecting 64 patients from the patients referred to the Neurology Clinic of Imam Hossein Hospital. They are randomly assigned to two groups.

Participants/Inclusion and exclusion criteria
inclusion criteria: Patients with BHS attacks at least 3 times a month, less than 6 years of age and above 6 months, normal growth and development, normal cardiac, cerebral and neurological examinations, electrolyte impairment, hypoglycemia and iron deficiency, lack of history of any seizure or neurological problem or epilepsy Exclusion criteria: inability to follow up, existence of drug reaction or any other problem, seizure or any neurological disorders during the study

Intervention groups
Patients (depending on the group in which they are treated) are treated with levetiracetam with a dose of 40 mg / kg / day and second group is treated with piracetam 100 mg / kg for 3 months.

Main outcome variables
The number and severity of the attacks before the start of treatment and monthly up to three months later

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190208042654N1**
Registration date: **2019-05-27, 1398/03/06**
Registration timing: **registered_while_recruiting**
Last update: **2019-05-27, 1398/03/06**
Update count: **0**

Registration date
2019-05-27, 1398/03/06

Registrant information
Name
Vahid Mansouri
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-16, 1397/12/25

Expected recruitment end date
2019-07-23, 1398/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Comparison of Levetiracetam and Piracetam efficacy on severe Breath Holding Spells; A Randomized Controlled clinical trial

Public title
The Comparison of Levetiracetam and Piracetam efficacy on severe Breath Holding Spells

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with severe breath holding attacks at least 3 times a month Aged less than 6 years and more than 6 months Normal growth and development Normal cardiovascular, cerebral and neurological examinations Not having electrolyte disturbances, hypoglycemia and iron deficiency Not having any seizure or neurological problem or epilepsy
Exclusion criteria:
Inability to follow up occurrence of any drug reaction or any other problem during treatment occurrence of seizure or any neurological disorders during the study

Age
From **6 months** old to **6 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
A total of 64 patients will be selected consecutively, if they meet the criteria for entry, from the patients admitted to the neurology clinic of Imam Hossein children hospital. Then, they are assigned randomly to two groups by binary blocks. The randomization process is done by using a random numbered table to reach the desired sample number.
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
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jarib Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-03-12, 1397/12/21
Ethics committee reference number
IR.MUI.MED.REC.1397.333

Health conditions studied

1

Description of health condition studied
Breath holding spell
ICD-10 code
R06.8
ICD-10 code description
Other abnormalities of breathing

Primary outcomes

1

Description
Number of breath holding spells
Timepoint
Before the intervention and monthly up to 3 months
Method of measurement
Questionnaire

2

Description
Severity of breath holding spells: Percentage of convulsive attacks
Timepoint
Before the intervention and monthly up to 3 months
Method of measurement
Questionnaire

Secondary outcomes

1

Description
EEG pattern
Timepoint
Before the intervention and 3 months later
Method of measurement
Electroencephalography

Intervention groups

1

Description
Intervention group: Levetiracetam: For 3 months, they are treated with Levetiracetam (100 mg/ml) with a dose of 40 mg/kg/day. Changes in the number of attacks and the percentage of convulsive attacks will be assessed during the three months.
Category
Treatment - Drugs

2

Description
Control group: Piracetam: They are treated with piracetam 100 mg/kg for 3 months. Changes in the number of attacks and the percentage of convulsive attacks will be assessed during the three months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hossein Hospital
Full name of responsible person
Mohammad Mehdi Salehi
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Emam Khomeini Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo Javanmard
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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
Esfahan University of Medical Sciences
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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad reza Ghazavi
Position
Assistant Professor
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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available