

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Country

Iran (Islamic Republic of)

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Email address

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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

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Hezar Jarib Ave

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Isfahan

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Isfahan

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

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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

Latest degree

Subspecialist

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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