

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation of therapeutic effects of single and divided dose of piracetam in patients with breath holding spells

Protocol summary

Summary

The aim of this study is evaluation of therapeutic effects of piracetam in single daily dose in compare with twice daily dose of 40mg/kg/day for treatment of severe spells. Inclusion criteria: Age of 6 months to three years; Frequent seizures more than two times a week; Severe seizures that lead to loss of consciousness. Exclusion criteria: History of seizures; History of heart disease; Anemia (hemoglobin less than 10.5). In this prospective clinical trial, children with severe BHS will be referred to our outpatient university clinics of pediatric neurology and will be randomized to single dose and dividing doses groups. Control group (Single dose) will receive single daily dose of 40mg/kg/day piracetam in the morning and intervention group (dividing dose) will receive 20mg/kg/dose of piracetam twice daily. Patients will be followed for four months. The number of severe attacks before and after treatments will be recorded. The data will be analyzed. All patients will fill in informed consent .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060612782N11**
Registration date: **2017-03-10, 1395/12/20**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-10, 1395/12/20

Registrant information

Name

Ali Mehrabi kushki

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effects of single and divided dose of piracetam in patients with breath holding spells

Public title

Therapeutic effects of single and divided doses of piracetam for children with breath holding spells

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria for the study included as follows: Age of 6 months to three years; Frequent seizures, more than two times a week; Severe seizures that lead to loss of consciousness Exclusion criteria included as follows: History of seizures; History of heart disease; Anemia (hemoglobin less than 10.5)

Age

From **6 months** old to **3 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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

Isfahan university of medical sciences, azadi square, Isfahan, Iran

City

isfahan

Postal code

81746-73461

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

IR.MUI.REC.1394.30814

Health conditions studied**1****Description of health condition studied**

breath holding

ICD-10 code

R06.8

ICD-10 code description

Other and unspecified abnormalities of breathing

Primary outcomes**1****Description**

number of breath holding

Timepoint

once in any month for 4 months

Method of measurement

ask from mother

Secondary outcomes**1****Description**

drug side effects

Timepoint

once in any month for 4 months

Method of measurement

examamination and ask from mother

Intervention groups**1****Description**

Control group: 40 mg/kg piracetam single dose daily

Category

Treatment - Drugs

2**Description**

Intervention group: 40 mg/kg Piracetam in two doses every 12 hours

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hosein hospital

Full name of responsible person

Dr Jafar Nasiri

Street address

Imam Hosein hospital, Imam Khomini street, Isfahan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr Mansour Siavash

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Vice Chancellor for research of Isfahan University of Medical Sciences, Isfahan University of Medical Sciences,

City
Isfahan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice Chancellor for research of Isfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
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Position
resident of pediatric

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty