Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 intervation 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

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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
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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
City
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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
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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