Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Can Piracetam control breath-holding spells and the symptoms of disease in children? A double blind RCT

Protocol summary

Summary

Background Breath holding spell is a type of syncope in which loss of consciousness may happen due to injury, fear, anger or frustration. No treatment for this illness has been offered yet. In this study, we evaluated the effect of Piracetam in controlling breath-holding spells (BHS) and its effect on controlling the symptoms of the disease. Methods The study was a double blind randomized clinical trial. Sixty one volunteer children with BHS from Bu- Ali hospital of Ardabil were recruited with Inclusion criteria: 1)Parental consent for participation in the plan 2) Normal EEG 3) absent of systematic disease 4) Normal growth and Development 5) History of breath- Holding spell and physical and neurological examination by pediatric neurologist. 6) No Electrolyte Abnormality (Hypoglycemia and Hypocalcaemia) Exclusion criteria: 1) Children with history of convulsion 2) Children that received Anticonvulsant drugs. 3) Delayed neurotic development 4) all Children with heart diseases 5) all children with anemia 6) Side effects of priacetam including true dizziness, convulsion, extra pyramidal sings, lethargy, headache, and sleepiness. Subjects were randomly allocated into two groups. The first group received Piracetam suspension (40 mg/kg twice a day), and the second group received placebo. Over 6 months, the patients were evaluated every 2 months .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010054872N1**
Registration date: **2010-12-09, 1389/09/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-12-09, 1389/09/18

Registrant information

Name
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Name of organization / entity
Lorestan University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Ardebil University of Medical Sciences

Expected recruitment start date

2007-04-30, 1386/02/10

Expected recruitment end date

2008-03-29, 1387/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Can Piracetam control breath-holding spells and the symptoms of disease in children? A double blind RCT

Public title

A comparative study of piracetam effect

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1)Parental consent for participation in the plan 2) Normal EEG 3) absent of systematic disease

4) Normal growth and Development 5)History of breath-Holding spell and physical and neurological examination by pediatric neurologist. 6) No Electrolyte Abnormality (Hypoglycemia and Hypocalcaemia) Exclusion criteria: 1) Children with history of convulsion 2) Children that received Anticonvulsant drugs. 3) Delayed neurotic development 4) all Children with heart diseases 5) all children with anemia 6) Side effects of priacetam including true dizziness, convulsion, extra pyramidal sings, lethargy, headache, sleepiness; gastrointestinal complication including nausea and vomiting, diarrhea, constipation, anorexia, increased weight

Age
From **1 year** old to **14 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **61**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee in Ardebil University of Medical Sciences

Street address
Ardebil University of Medical Sciences

City
Ardebil

Postal code

Approval date
2008-02-02, 1386/11/13

Ethics committee reference number
6568

Health conditions studied

1

Description of health condition studied
breath holding spell

ICD-10 code
R06.8

ICD-10 code description
Other and unspecified abnormalities of breathing

Primary outcomes

1

Description
interval time between BHS

Timepoint
before prevention and every 2 month in 6 month

Method of measurement
questionnaire & exam

2

Description
BHS duration

Timepoint
before prevention and every 2 month in 6 month

Method of measurement
Filling a questionnarie by asking questions from parents & exam

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: administration of piracetam in 6 mounth period with dose of 40/mg/kg/day

Category
Treatment - Drugs

2

Description
contorol group: administration of placebo in 6 mounth period

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Pediatric Hospitals in the Imam Khomeini and BoAli

Full name of responsible person
Dr Mehrdad Mirzarahimi

Street address

City
Ardebil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardeabil University of Medical Sciences.
Full name of responsible person
Dr Mehrdad Mirzarahimi
Street address
Faculty of Medicine. Pediatrics Department
City
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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
Ardeabil 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