Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical Efficacy of Piracetam on the Treatment of Breath _Holding Spells

Protocol summary

Summary

Our objective was to determine the efficacy of Piracetam on the treatment of breath holding spells. Inclusion criteria: 1- History of breath- Holding spell 2- minimum age 6 month and maximum 3 years old 3- Normal EEG3 4- absent of systematic disease 5- Normal growth and Development 6- No history of epilepsy in family members 7- No Electrolyte Abnormalities (Hypoglycemia & 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. Hundred patients with Breath Holding spell were randomized in two groups. First group received placebo and the other received 40 mg/kg/day priacetam. Then we evaluated the number of breath holding spell before intervention, 2 weeks and 2 month after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801231808N1**
Registration date: **2009-06-29, 1388/04/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-06-29, 1388/04/08

Registrant information

Name

Ali Abbaskhanian

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1223 3010

Email address

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences and Health Services

Expected recruitment start date

2009-04-15, 1388/01/26

Expected recruitment end date

2009-06-22, 1388/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Efficacy of Piracetam on the Treatment of Breath _Holding Spells

Public title

Clinical Efficacy of Piracetam on the Treatment of Breath _Holding Spells

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) History of breath- Holding spell and physical and neurological examination by pediatric neurologist. 2) Minimum age 6 month and maximum 3 years old 3) Normal EEG 4) absent of systematic disease 5) Normal growth and Development 6) No history of epilepsy in family member 7) 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, sleepy; gastrointestinal

complication including nausea and vomiting, diarrhea, constipation, anorexia, increased weight

Age
From **1 year** old to **3 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Mazandaran University of Medical Sciences and Health Services

Street address
Imam Sq, Joybar 3way, Start of valiye asr highway

City
Sari

Postal code

Approval date
empty

Ethics committee reference number
88-9

Health conditions studied

1

Description of health condition studied
Breath-holding spells

ICD-10 code
R06.8

ICD-10 code description
Other and unspecified abnormalities of breathing

Primary outcomes

1

Description
the number of Breath-holding spell

Timepoint
before prevention and 2 weeks after prevention

Method of measurement
questionarie of parents

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: administration of piracetam in 2 mounth period with dose of 40/mg/kg/day

Category
Treatment - Drugs

2

Description
contorol group: administration of placebo in 2 mounth period

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Bouali sina hospital - pediateric Department

Full name of responsible person
Ali Abbaskhanian

Street address
Emam sq - Pasdaran Blv

City
Sari

2

Recruitment center

Name of recruitment center
Tuba clinic

Full name of responsible person
Ali Abbaskhanian

Street address

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences and Health Services

Full name of responsible person
Ali Abbaskhanian

Street address
Boalisina hospital, pediateric department - Imam sq - Pasdaran Blv

City
Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mazandaran University of Medical Sciences and Health Services

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
Mazandaran Univercity of Medical sciences and Health ervices

Full name of responsible person
Motahareh kheradmand

Position
Master of science in nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Pediatric neourologist

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Person responsible for updating data

Contact

Name of organization / entity
Mazandaran Univercity of medical sciences and Health Services

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Pediatric resident

Other areas of specialty/work

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City
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Postal code

Phone

Fax

Email

Web page address

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