

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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 EEG 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 piracetam. 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

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Iran (Islamic Republic of)

Phone

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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 piracetam 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 month 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

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Person responsible for updating data

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Other areas of specialty/work

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City

Sari

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