

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the efficacy of Piracetam and probiotic-Piracetam in cyanotic breath holding spells in children

Protocol summary

Registration timing: **prospective**

Study aim

Comparison of the efficacy of Piracetam and probiotic-Piracetam in cyanotic breath holding spells in children

Last update: **2021-05-30, 1400/03/09**

Update count: **0**

Design

Clinical trial with two parallel groups, without blindness, randomised, phase 2 on 58 patients, in block randomization method with the size of 4 and 6, Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>).

Registration date

2021-05-30, 1400/03/09

Registrant information

Name

Shamim Valibak

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Settings and conduct

The aim of the study is comparison of the efficacy of Piracetam and probiotic-Piracetam in cyanotic breath holding spells in 58 children refer to Amirkabir hospital of Arak city. They will be divided into 2 groups (Piracetam or probiotic-Piracetam) randomly.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children with cyanotic breath holding spells diagnosed by neurologist. Children who have informed consent filling by their parents. Non-inclusion criteria: Children using corticosteroid drugs Children with underlying disease such as cyanotic heart disease Children with iron deficiency anemia

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

In Piracetam group 55 mg/kg of Piracetam tablet and in Probiotic-Piracetam group both of 1 sachet of reuteflor (300 mg of liofilizate cells of Lactobacillus reuteri) and 55 mg/kg of Piracetam tablet will be given to children, daily for 1 month.

Scientific title

Comparison of the efficacy of Piracetam and probiotic-Piracetam in cyanotic breath holding spells in children

Main outcome variables

Frequency (number) of breath holding spells

Public title

Comparison of the efficacy of Piracetam and probiotic-Piracetam in cyanotic breath holding spells in children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049175N8**

Registration date: **2021-05-30, 1400/03/09**

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with cyanotic breath holding spells diagnosed by neurologist Children who have informed consent filling by their parents

Exclusion criteria:

Children using corticosteroid drugs Children with underlying disease such as cyanotic heart disease Children with iron deficiency anemia

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated into two groups using a permuted balanced block randomization method with the size of blocks 4 and 6. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Concealment is also guaranteed due to the use of specific codes that are obtained by the website.

Blinding (investigator's opinion)

Not 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 Arak University of Medical Sciences

Street address

Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Sardasht street

City

Arak

Province

Markazi

Postal code

3848176341

Approval date

2021-05-16, 1400/02/26

Ethics committee reference number

IR.ARAKMU.REC.1400.026

Health conditions studied

1

Description of health condition studied

Breath holding spells

ICD-10 code

R06.8

ICD-10 code description

Other abnormalities of breathing

Primary outcomes

1

Description

Frequency (number) of cyanotic breath holding spells

Timepoint

Daily

Method of measurement

Filling the questionnaire by the mother

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:In Piracetam group 55 mg/kg of Piracetam tablet will be given to children, daily for 1 month.

Category

Treatment - Drugs

2

Description

Intervention group:In Probiotic-Piracetam group both of 1 sachet of Farabiotic Reuteflor (300 mg of liofilizate cells of Lactobacillus reuteri) and 55 mg/kg of Piracetam tablet will be given to children, daily for 1 month.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr. Fakhredin Shariatmadari

Street address

Parastar square, Shiroudi street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Assistance of research and technology of Arak university of medical science-Dr Alireza Kamali

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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

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mojtaba Hashemi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Fakhredin Shariatmadari

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr.Shamim Valibak

Position

General physician non-faculty

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available