Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

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

Protocol summary

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

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/).

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 devided into 2 groups (Piracetam or probiotic-Piracetam) randomly.

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

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.

Main outcome variables
Frequency (number) of breath holding spells

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201028049175N8**
Registration date: **2021-05-30, 1400/03/09**
Registration timing: **prospective**

Last update: **2021-05-30, 1400/03/09**
Update count: **0**

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

Registrant information

Name
Shamim Valibak

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 86 3417 3502

Email address
sh.valibak@yahoo.com

Recruitment status
Recruitment complete

Funding source

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

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

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

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

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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
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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