Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The efficacy of piracetam on children with global developmental delay

Protocol summary

Study aim
A) The general aim of the project: to investigate the effect of Piracetam on children with global developmental delay

Design
Forty children with GDD enter the phase 2 clinical trial. No blinding is done, and the study has no control group.

Settings and conduct
Forty eligible patients referred to the neurology and neurodevelopmental clinics of Zahra Mardani Azari Hospital were given 40 mg of piracetam syrup per their body weight. Their ASQ results, taken before the start of treatment, 3 months after the start of treatment, and 6 months after the beginning of treatment, are compared.

Participants/Inclusion and exclusion criteria
inclusion criteria: 1) chronological age below 5 years and 2) developmental delay in more than or equal to two developmental areas and exclusion criteria include: 1) having metabolic disease or underlying structural disorder, 2) lack of consent It is informed to participate in the study.

Intervention groups
Eligible patients will be given 40 mg of piracetam syrup per body weight per day, and their ASQ results will be compared before, 3 months, and 6 months after starting treatment.

Main outcome variables
1) Improving performance in the field of fine movements 2) Improving performance in the field of gross movements 3) Improving communication performance 4) Improving performance in problem-solving 5) Improving performance in the personal-social field

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180404039187N14**
Registration date: **2025-06-06, 1404/03/16**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-06, 1404/03/16**
Update count: **0**

Registration date
2025-06-06, 1404/03/16

Registrant information

Name
Elnaz Shaseb

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-19, 1403/10/30

Expected recruitment end date
2025-09-22, 1404/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of piracetam on children with global developmental delay

Public title
The efficacy of piracetam on children with global developmental delay

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age below 5 years and above 2 months Developmental delay in more than or equal to two developmental domains
Exclusion criteria:
Having a metabolic disease or underlying structural disorder Lack of informed consent to participate in the study

Age
From **2 months** old to **5 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran National Committee for Ethics in Biomedical Research

Street address
Khavaran Twon, Zahra Mardani Azari Child Hospital, Tabriz, East Azarbaijan

City
tabriz

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East Azarbaijan

Postal code
5267153124

Approval date
2024-03-10, 1402/12/20

Ethics committee reference number
IR.TBZMED.PHARMACY.REC.1402.064

Health conditions studied

1

Description of health condition studied
global developmental delay

ICD-10 code
F83

ICD-10 code description
Specific developmental disorder of motor function

Primary outcomes

1

Description
1) Improvement of performance in the area of fine movements 2) Improvement of performance in the area of gross movements 3) Improvement of performance in the area of communication 4) Improvement of performance in the area of problem-solving 5) Improvement of performance in the personal-social area

Timepoint
Evaluation of the developmental form of the ASQ at the beginning of the study, 3 months, and 6 months after the start of the drug

Method of measurement
The effect of Piracetam on improving the development of a person, which is evaluated by the ASQ developmental questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In this study, 40 patients with developmental delay in more than or equal to 2 developmental areas are selected from among the patients referred to the pediatric neurology clinics and the Comprehensive Child Development Center. For these patients, after obtaining informed consent, the Iranian brand Piracetam syrup with the same name, Piracetam, is prescribed at a dose of 40 mg/kg/day once daily. Piracetam belongs to the racetam group, with the chemical name 2-oxo-1-pyrrolidine acetamide. This drug is a cyclic derivative of the neurotransmitter GABA and has the same 2-oxo-pyrrolidone basic structure as pyroglutamic acid. Piracetam is a positive allosteric modulator of the AMPA receptor, acting on ion channels or ion carriers, resulting in increased neuronal excitability. Piracetam affects NMDA glutamate receptors, which are involved in learning and memory processes, through muscarinic cholinergic receptors (ACh), which are involved in memory processes. This drug has been shown to increase oxygen consumption in the brain. The mother is given an age-appropriate ASQ form and is advised to practice, repeat, and teach the age-appropriate activities on the form with her child. Three months later, and six months after starting piracetam, the ASQ forms are completed by the same individual, and their results are compared with those on the previous forms. An improvement in the ASQ score of more than one

standard deviation (SD) is considered a response to treatment.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
children Zahra Mardani Azari Hospital

Full name of responsible person
Bita Poorshiri

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Zahra Mardani Azari Children's Hospital, Zaranq Road, Khavaran Town, Tabriz, East Azerbaijan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Vice-chancellor

Full name of responsible person
Dr. Parviz Shahabi

Street address
Golgasht Street / Tabriz University of Medical Sciences, Central Building No. 2 / Third Floor, Research and Technology Office/Tabriz/IRAN

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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
Research Vice-chancellor

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
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Bita Poorshiri

Position
assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available