

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison the effect of Piracetam versus placebo on control of attention deficit-hyper activity disorder symptoms in Iranian children and adolescents, a double blind randomized clinical trial

Protocol summary

Summary

In this research, we intended to study the effect of Piracetam- a cognitive enhancer & brain blood flow enhancer with glutamergic effects - on symptom control of ADHD. This study is a double blind placebo controlled clinical trial. With block randomization method; 36 participants randomly divided in to case & control groups. Both groups will receive Methylphenidate as a standard treatment. Then drug or placebo will prescribed up to 70 mg/kg/day additionally. At the beginning of study, 3 & 6 weeks latter 3 questionnaire include Parent's conners questionnaire, CGAS & Rachel & Klein Side effects Form will completed individually. Finally, the gathered data will analyzed statistically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303036923N2**

Registration date: **2013-08-01, 1392/05/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-01, 1392/05/10

Registrant information

Name

Elham Shirazi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2209 5680

Email address

eshirazi@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research Tehran University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-12-21, 1392/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Piracetam versus placebo on control of attention deficit-hyper activity disorder symptoms in Iranian children and adolescents, a double blind randomized clinical trial

Public title

Comparison the effect of Piracetam versus placebo on control of Attention deficit-hyper activity disorder symptoms.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 6-16; Diagnosis of ADHD for the first time Exclusion criteria : IQ<70 ; Having other chronic medical illnesses; Be under other medications; Any serious or severe complication during study; Refusal of child or parent to continue the study

Age

From **6 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 36

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**

Vice chancellor for Research Tehran University of Medical Sciences

Street address

Vice chancellor for Research Tehran University of Medical Sciences, 7th Floor, Central Building of Tehran University of Medical Sciences, Corner of Qods St, Keshavarz Blvd, Tehran, Iran

City

Tehran

Postal code**Approval date**

2013-07-01, 1392/04/10

Ethics committee reference number

19912

Health conditions studied**1****Description of health condition studied**

Attention deficit-hyperactivity disorder

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes**1****Description**

Attention, Impulsivity & Behavioral indecies

Timepoint

At the begining,3 weeks later & 6 weeks later

Method of measurement

Conner's parents questionnaire

2**Description**

Child's general function

Timepoint

At the begining of study , 3 weeks later , 6 weeks later

Method of measurement

CGAS questionnaire

Secondary outcomes**1****Description**

Drug complication

Timepoint

3 weeks after begining of the study & 6 weeks later

Method of measurement

Rachell & klein Side effects Form

Intervention groups**1****Description**

Intervention group will receive 70 mg/kg/day of Piracetam syrup (product of Daroo pakhsh company which contains 33.3 g/dl of drug) every morning , half an hour after taking Methylphenidate tablet.

Category

Treatment - Drugs

2**Description**

Control group will receive 70 mg/kg/day of placebo (Sucrose solution in the same package and same dilution as Piracetam syrup) half an hour after taking their Methylphenidate tablet.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Institute of Psychiatry

Full name of responsible person

Dr Maryam Akbari, Psychiatry Resident

Street address

Tehran Institute of Psychiatry, Shahid Mansouri St, Niayesh St, Sattarkhan St, Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Ali Asghar Children Hospital

Full name of responsible person

Dr Elham Shirazi, Associate Professor, Board of
Subspeciality of Child and Adolescent Psychiatry

Street address

Ali Asghar Children Hospital, Zafar St, Modarres Ave,
Tehran , Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for Research Tehran University of
Medical Sciences

Full name of responsible person

Dr Jalili

Street address

Vice chancellor for Research Tehran University of
Medical Sciences, 7th Floor, Central Building of
Tehran University of Medical Sciences, Corner of Qods
St, Keshavarz Blvd, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for Research Tehran University of Medical
Sciences

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**

Tehran Institute of Psychiatry

Full name of responsible person

Dr Maryam Akbari

Position

Psychiatry Resident

Other areas of specialty/work**Street address**

Tehran Institute of Psychiatry, Shahid Mansouri St,
Niayesh St, Sattarkhan St, Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 6655 1515

Fax**Email**

maryam1135@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran Institute of Psychiatry

Full name of responsible person

Dr Elham Shirazi

Position

Associate Professor, Board of Subspeciality of Child
and Adolescent Psychiatry

Other areas of specialty/work**Street address**

Tehran Institute of Psychiatry, Shahid Mansouri St,
Niayesh St, Sattarkhan St, Tehran, Iran.

City

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+98 21 6655 1515

Fax**Email**

eshirazi@iums.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Tehran Institute of Psychiatry

Full name of responsible person

Dr Maryam Akbari

Position

Psychiatry Resident

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Tehran Institute of Psychiatry, Shahid Mansouri St,
Niayesh St, Sattarkhan St, Tehran, Iran

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Postal code**Phone**

+98 21 6655 1515

Fax**Email**

maryam1135@yahoo.com

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