

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 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 be prescribed up to 70 mg/kg/day additionally. At the beginning of study, 3 & 6 weeks later 3 questionnaires include Parent's Conners questionnaire, CGAS & Rachel & Klein Side effects Form will be completed individually. Finally, the gathered data will be 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 &amp; Behavioral indecies

**Timepoint**

At the begining,3 weeks later &amp; 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 &amp; 6 weeks later

**Method of measurement**

Rachell &amp; 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**

Tehran

**Postal code**

**Phone**

+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

**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**

## **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*