

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Efficacy of pramipexole treatment and methylphenidate in children with attention deficit hyperactivity disorder, compared with placebo and methylphenidate

#### Protocol summary

##### Study aim

Investigating the effect of primexol and methylphenidate combination on patients suffering from Attention Deficit Hyperactivity Disorder (ADHD)

##### Design

A parallel, double-blind, randomized clinical trial with control group; community based and pragmatic. There will be two groups of drugs including primaxyl and placebo.

##### Settings and conduct

This study will be done in Ahvaz Golestan Hospital. Researchers and patients will not know about their received medication.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 6 to 12 years whose condition is confirmed by the Conner test Exclusion criteria: There is a psychiatric disorder and other medical conditions

##### Intervention groups

Intervention group: The starting dose of methylphenidate will be 0.3mg / kg in two divided doses and will be increased to 1mg / kg based on the need. Pramipexole starts at 0.125 mg per night and will be increased to 0.5 mg. The treatment response will be measured with the Conner's questionnaire before treatment and after 2, 4, 6, 8, 10, and 12 weeks. Control group: The control group will receive capsules that are similar to primiplex in shape,color and smell

##### Main outcome variables

Attention deficit hyperactivity score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100520003979N7**

Registration date: **2018-06-11, 1397/03/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-11, 1397/03/21**

Update count: **0**

##### Registration date

2018-06-11, 1397/03/21

##### Registrant information

###### Name

Forugh Riahi

###### Name of organization / entity

Ahvaz Jundishapour University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3374 3038

###### Email address

riahi-f@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-22, 1397/03/01

##### Expected recruitment end date

2018-08-23, 1397/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of pramipexole treatment and methylphenidate in children with attention deficit hyperactivity disorder, compared with placebo and methylphenidate

**Public title**

Efficacy of pramipexole treatment and methylphenidate for attention deficit hyperactivity disorder

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age of children aged 6 to 12 years Having diagnostic criteria based on IV-IRDSM and Conners test

**Exclusion criteria:**

The presence of other medical conditions (heart problem, kidney failure, epilepsy, etc.) The presence of other serious psychiatric disorders such as mood disorders, penetrating disorders, and The presence of symptoms of mental disability a history of seizure

**Age**

From **6 years** old to **12 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **10**

Actual sample size reached: **10**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization was done by random number table

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patient and the therapist are not informed about the medicine they received.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ahvaz JundiShapour University of Medical Sciences  
Ethics Committee

**Street address**

Golestan Blvd, Ahvaz, Khoozestan

**City**

Ahvaz

**Province**

Khoozestan

**Postal code**

6135715794

**Approval date**

2017-10-07, 1396/07/15

**Ethics committee reference number**

IR.AJUMS.REC.1396.496

**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 Deficit Hyperactivity Disorder.

**Timepoint**

Before intervention- the end of second, fourth and sixth, eighth, tenth, twelfth weeks of the study

**Method of measurement**

The Conner's parent rating scale

**Secondary outcomes**

empty

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

Intervention group: children will be treated with Methylphenidate and Pramipexole during 12 weeks. The starting dose of methylphenidate will be considered to be 0.3mg / kg in two divided doses and will be increased to 1mg/kg based on need. Pramipexole starts with 0.125 mg every night. Then the dose will gradually be increased based on clinical response and tolerance to side effects. The final dose for pramipexole will be up to 0.5mg a day.

**Category**

Treatment - Drugs

**2****Description**

Control group: children will be treated with methylphenidate and placebo during 12 weeks. Placebo pill are will be similar to shape, color, smell and taste are like pramipexole.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Adolecent Psychiatry Clinic, Golestan Hospital

**Full name of responsible person**

Ashraf Tashakori

**Street address**

Psychiatry Group, Golestan Hospital,Ahvaz

**City**

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**Phone**

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tashakori\_doctor@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Ashraf Tashakori

**Street address**

Golestan hospital,Farvardin Blvd, Ahvaz ,Khouzestan

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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**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Zohre Khozoeii Ashekzari

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

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Golestan hospital,Golestan Blvd,Ahvaz

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Position**

Resident

**Latest degree**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Zohre khozuey ashkezari

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Email**

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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