

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Summary

Aim of this study is Evaluating the effects of combining drugs pramipexole and methylphenidate in the treatment of Attention Deficit Hyperactivity Disorder children. Children should be 6-12 years old and diagnostic criteria according to DSM IV-IR and have Conners test. In case of any medical conditions or mental disability or a history of seizures other than seizures associated with fever, are excluded. The sample is 10 children of ADHD that referred to Golestan Hospital. Conners Scale to help identify systematically used in ADHD and in both teacher and parent designed. Patients treated with methylphenidate and pramipexole during 6 weeks. The starting dose of methylphenidate considered to be 0.3mg / kg in two divided doses and increase based on the need to 1mg / kg. Pramipexole starts with Pramipexole at nights. Then gradually increase the dose based on clinical response and tolerability of side effects. And the final dose of up to 0.5mg pramipexole a day. As well as placebo in terms of shape, color, smell and taste will be like pramipexole

General information

Acronym

Attention Deficit Hyperactivity Disorder

IRCT registration information

IRCT registration number: **IRCT201612253979N6**

Registration date: **2017-01-24, 1395/11/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-01-24, 1395/11/05

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

Vice chancellor for research Ahvaz Jundishapour University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-22, 1396/04/01

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 in children with attention deficit hyperactivity disorder, compared with placebo and methylphenidate.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children 6-12 years old; Having diagnostic criteria and testing Connors. Exclusion criteria: medical conditions such as kidney failure and epilepsy; psychiatric disorders with a focus on DSM IV-TR; mental disability; history of seizures other than seizures associated with fever; need for dopaminergic drugs, levodopa, ranitidine, cimetidine

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **10**

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

Ahvaz JundiShapour University of Medical Sciences
Ethics Committee

Street address

Golestan Blvd- Ahvaz

City

Ahvaz

Postal code

Approval date

2016-07-23, 1395/05/02

Ethics committee reference number

IR.AJUMS.REC.1395.355

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 weeks of the study

Method of measurement

The Conner's parent rating scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: children treat with methylphenidate and pramipexole during 6 weeks. The starting dose of methylphenidate considered to be 0.3mg / kg in two divided doses and increase to 1mg/kg based on need. Pramipexole starts with dose of 0.125mg in nights Then gradually increase the dose based on clinical response and tolerability of side effects. The final dose of up to 0.5mg pramipexole a day.

Category

Treatment - Drugs

2

Description

Treatment groups: children 6 weeks will be treated with methylphenidate and placebo. Placebo pill shape, color, smell and taste will be like pramipexole.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Child and Adolescent Psychiatry Clinic, Golestan Hospital

Full name of responsible person

Forugh Riahi

Street address

Psychiatry Group, Golestan Hospital

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Devision, Ahvaz Jondishapoor Medical University

Full name of responsible person

Behzad Sharif Makhmal Zade

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research Devision, Ahvaz Jondishapoor Medical University

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Forough Riahi

Position

Assistant Professor

Other areas of specialty/work

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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