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

Study aim
Investigating the effect of primepxol 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 primaxyxol 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
Khouzestan
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
Befor 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
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3038
Email
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 ,Khoozestan
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3038
Email
tashakori_doctor@yahoo.com

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
Street address
Golestan hospital,Golestan Blvd,Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3038
Email
z.khozuey@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Zohre khozuey Ashkezari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Golestan Blvd, Ahvaz,Khoozestan
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3038
Email
z.khozuey@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Zohre khozuey ashkezari
Position
resident

Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Golestan Blvd, Ahvaz, Khoozestan
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3374 3038
Email
Z.khozuey@yahoo.com

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