Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparing the efficacy of Agomelatine and Ritaline in treating children with ADHD in a randomized double-blinded clinical trial

Protocol summary

Summary
The aim of the present study is to evaluate the efficacy of Agomelatine on ADHD in children and adolescents through a double-blind, randomized, controlled trial. 50 outpatients, including 6-17 years old who clearly meet the DSM-IV-TR diagnostic criteria for ADHD(based on duiagnosis of a child psychiatrist) will be randomly assigned to receive Agomelatine tablets (25mg/day) or methylphenidate (10-20 mg/day for those who are less than 30 Kg and 30 mg/day for those who are more than30 Kg) for 6 weeks. The primary outcome measure is the Teacher and Parent ADHD Rating Scale. Patients will be assessed by a child psychiatrist at baseline, 14, 28 and 42 days after the medication started.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT201312181556N55**
Registration date: **2013-12-23, 1392/10/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date
2013-12-23, 1392/10/02

Registrant information

Name
Shahin Akhondzadeh
Name of organization / entity
Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2014-01-05, 1392/10/15
Expected recruitment end date
2015-07-05, 1394/04/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the efficacy of Agomelatine and Ritaline in treating children with ADHD in a randomized double-blinded clinical trial

Public title
Agomelatine in the treatment of ADHD
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: diagnosis of ADHD based on DSM-IV and age between 6-17 years old. Exclusion criteria: receiving of any psychotropics drugs during past two weeks; presence of any psychiatric disorders or mental retardation (I.Q. <70) except for ODD; history of allergy to Agomelatine or Ritaline; presence of any medical problem including cardiovascular diseases; presence of uncontrolled seizures; systolic blood pressure more than 120 mm Hg; resting pulse rate less than 60/minute or more than 115/minute; liver enzymes more than normal range.
Age
From **6 years** old to **17 years** old

Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
Keshvarz Blvd
City
Tehran
Postal code
Approval date
2013-12-06, 1392/09/15
Ethics committee reference number
23222

Health conditions studied

1

Description of health condition studied
Disturbance of activity and attention
ICD-10 code
F90.0
ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description
Severity of ADHD
Timepoint
Week 0 (before treatment) and Weeks 2, 4 and 6 after treatment
Method of measurement
Teacher and Parent ADHD Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Tablet Agomelatine 25 mg/day as intervention group for 6 weeks
Category
Treatment - Drugs

2

Description
Tablet Ritalin 20-30 mg/kg/day for 6 weeks as control group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Roozbeh Hospital
Full name of responsible person
Dr. Shahin Akhondzadeh
Street address
South Kargar Sreeet, Roozbeh Hospital
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Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr masoud yunesian
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Keshvarz Blvd
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
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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