Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Buspirone VS ritaline in the treatment of ADHD: a randomized clinical trial

Protocol summary

Summary

The aim of the present study is to evaluate the efficacy of Buspirone on ADHD in children and adolescents through a double-blind, randomized, controlled trial. 40 outpatients, including 6-17 years old who clearly meet the DSM-IV-TR diagnostic criteria for ADHD will be randomly assigned to receive Buspirone tablets (20mg/day) or methylphenidate (20 mg/day for those who are <30 Kg and 30 mg/day for those who are >30 Kg) for 6 weeks. The primary outcome measure is the Teacher and Parent ADHD Rating Scale- IV. Patients will be assessed at baseline as well as 3 and 6 weeks after the medication started.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011101556N17**
Registration date: **2010-12-04, 1389/09/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-12-04, 1389/09/13

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

1-Tehran University of Medical Sciences 2-Kurdistan University of Medical Sciences, Sanandaj, Iran

Expected recruitment start date

2010-04-20, 1389/01/31

Expected recruitment end date

2012-04-20, 1391/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Buspirone VS ritaline in the treatment of ADHD: a randomized clinical trial

Public title

Comparison of Buspirone and Ritaline in the treatment of ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Diagnosis of ADHD based on DSMIV age between 6-17 Exclusion Criteria: receiving of any psychotropics drugs during past two weeks, , serum creatinin >2, hepatic failure, presence of seizures, development of extrapyramidal signs, development of serotonin syndrome

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: **40**
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
Tehran University of Medical Sciences
Street address
Keshavarz Blvd
City
Tehran
Postal code
Approval date
2010-03-06, 1388/12/15
Ethics committee reference number
8643

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 3 and 6 after treatment
Method of measurement
Teacher and Parent ADHD Rating Scale

Secondary outcomes

empty

Intervention groups

1

Description
Tablet Buspirone 20 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
Prof. Mohammad Reza Mohhamadi
Street address
south kargar street
City
Tehran

2

Recruitment center
Name of recruitment center
Qhods Hospital- Kurdistan University of Medical Sciences
Full name of responsible person
Dr. Farzin Rezaei
Street address
Pasdaran Blvd- Qhods hospital - Sanandaj
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Akbar Fotouhi
Street address
Keshavarz Blvd
City
Tehran

Grant name
Grant code / Reference number
8643
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
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

2

Sponsor
Name of organization / entity
Kurdistan University of Medical Sciences
Full name of responsible person
Dr Ataollah Heydari
Street address
Pasdaran Blvd-Kurdistan university of Medical Sciences-Deputy of research- Sanandaj
City
Sanandaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kurdistan University of Medical Sciences
Proportion provided by this source
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

Person responsible for scientific inquiries

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Name of organization / entity
Tehran University of Medical Sciences
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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