

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### comparison of bupropion and ritaline in the treatment of children with ADHD: a double blind trial

#### Protocol summary

##### Summary

The aim of the present study is to evaluate the efficacy of Bupropion 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 Bupropion tablets (200 mg/day for those who are <30 Kg and 300 mg/day for those who are >30 Kg) 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 by a psychiatrist at baseline, as well as 3 and 6 weeks after the medication started.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012021556N18**

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

+98 21 5541 2222

##### Email address

s.akhond@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

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

##### Expected recruitment start date

2010-05-14, 1389/02/24

##### Expected recruitment end date

2011-11-14, 1390/08/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

comparison of bupropion and ritaline in the treatment of children with ADHD: a double blind trial

##### Public title

comparison of bupropion and ritaline in the treatment of children with ADHD

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: Diagnosis of ADHD based on DSM-IV, age between 6-17 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 Bupropion, presence of any medical problem including cardiovascular diseases, presence of uncontrolled seizures, systolic blood pressure>125, resting pulse rate <60/minute or >115/minute, zinc deficiency, lead intoxication

##### 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**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Keshavarz Blvd

**City**

Tehran

**Postal code****Approval date**

2010-04-14, 1389/01/25

**Ethics committee reference number**

9745

**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 Bupropion(200 to 300 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**

Roozbeh Hospital

**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****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****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

Prof. of Clinical Psychopharmacology

**Other areas of specialty/work****Street address**

Roozbeh Hospital-South Karegar street

**City**

Tehran

**Postal code****Phone**

+98 21 5541 2222

**Fax**

+98 21 5541 9113

**Email**

s.akhond@sina.tums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

Prof. of Clinical Psychopharmacology

**Other areas of specialty/work****Street address**

Roozbeh Hospital -south Kargar street

**City**

Tehran

**Postal code****Phone**

+98 21 5541 2222

**Fax****Email**

s.akhond@sina.tums.ac.ir

**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*