

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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