# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## Comparison of Donepezil and Placebo as adjunctive therapy with Ritalin on Executive Functioning of children with Attention Deficit Hyperactivity Disorder

## Protocol summary


**Summary**

This study compares the effectiveness of Donepezil with placebo on improving the executive functions of children with attention deficit hyperactivity disorder (ADHD). The target population is ADHD child patients who refer to Children Psychiatric Clinic of Rozbeh Hospital. Inclusion criteria : 1. Age of six to twelve years; 2. IQ above 90. Exclusion criteria : 1. an intervening physical disorder; 2. a major psychiatric disease. Basic assessments: 1. Semi-structured diagnostic interviews for mood disorders and schizophrenia 2. Conners parent rating scale 3. Wechsler intelligence scale 4. CANTAB computer test of executive functions 5. General clinical scale for assessing the severity of symptoms of ADHD The primary outcome: the severity of ADHD symptoms The secondary outcome: changes in mean scores of CANTAB test for executive functions 0.5 mg Ritalin per kg per day is given to all children. Study group receives Donepezil and the control group receives placebo. Donepezil: 2.5 mg starting dose gradually reaches to ten milligrams per night by controlling the side effects. Double-blinded method: (1) the participants are grouped by an assistant who is unaware of the treatment profile in the control or study group. The doctor that prescribes medication and visits the patient, the patient, and his/her family are unaware of the drug type. (2) First, the arrangement of participants is determined by using random numbers table for each group. Then, based on the order of referral of children, each enters into the specified group. (3) Donepezil and placebo are produced as identical tablets in similar packages by another assistant in the pharmacy and coded with 1 and 2. The patients receive the drug based on the code. Sample size: according to the results of previous studies, the sample size is calculated 20 for each group.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016042027506N1**
Registration date: **2016-05-16, 1395/02/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2016-05-16, 1395/02/27

**Registrant information**


**Name**
parisa pakdel
**Name of organization / entity**
fellow
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 5541 9154
**Email address**
p-pakdel@razi.tums.ac.ir


**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor for research,Tehran University of Medical Science

**Expected recruitment start date**

2016-05-04, 1395/02/15

**Expected recruitment end date**

2016-09-05, 1395/06/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Comparison of Donepezil and Placebo as adjunctive therapy with Ritalin on Executive Functioning of children with Attention Deficit Hyperactivity Disorder

**Public title**
Donepezil effect in Executive Function of Hyperactivity Disorder

**Purpose**
Treatment

**Inclusion/Exclusion criteria**
Inclusion criteria: 1. Age of six to twelve years; 2. DSM-5 criteria for a diagnosis of ADHD; 3. IQ above 90.
Exclusion criteria: 1. an intervening physical disorder such as neurological disorders, a record of severe allergic reaction to Ritalin or Donepezil, record of heart disease; 2. a major psychiatric disease such as mood disorders, psychotic disorders, substance abuse.

**Age**
From **4 years** old to **12 years** old

**Gender**
Both

**Phase**
2

**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**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee Tehran University of Medical Sciences

**Street address**
Central Organization of University, Ghods Ave, Keshavarz Blvd.

**City**
Tehran

**Postal code**

**Approval date**
2016-04-12, 1395/01/24

**Ethics committee reference number**
IR-TUMS-REC-1395-2384

## 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 Attention deficit: disorder with hyperactivity hyperactivity disorder syndrome with hyperactivity Excl.: hyperkinetic disorder associated with conduct disorder

## Primary outcomes

### 1

**Description**
Change in severity of symptoms of Attention Deficit Hyperactivity Disorder, according to the opinion of therapist and family.

**Timepoint**
weeks zero, four, and eight.

**Method of measurement**
Conners Parent Scale and General Clinical Assessment

## Secondary outcomes

### 1

**Description**
Change in mean scores of the CANTAB computer test of executive functions (working memory, planning skills, capacity of working memory, response inhibition and impulse control, measuring argument).

**Timepoint**
weeks zero, four, and eight

**Method of measurement**
CANTAB computer test

## Intervention groups

### 1

**Description**
Intervention group (1): After the initial evaluation(Connor's parent questionnaire, IQ test,CANTAB test) and gaining the consent of the children and their parents, Ritalin medication at 0.5 milligrams per kilogram of body weight begins. This dosage is divided into hours of 8 am, 12 am, and 4 pm. In addition to Ritalin, this group received Donepezil. Donepezil is among the acetylcholinesterase inhibitors. In this study, Donepezil tablet manufactured by Pfizer Germany Aricept commercial name has been used and is administered orally. Dosage Week Zero: studies have

shown that 2.5 mg is easily tolerated, so the dose starts of 2.5 mg at night and will be raised to 5 mg after 2 weeks. After two weeks, digestive problems and irritable or other complications are asked through a phone call to family. If no report of side effects was given, the dose remains constant until the end of week 4. Week 4: patients refer to hospital in person. Drug side effects questionnaire and a Connor's parent questionnaire are asked to be filled, then the CANTAB test is administered. After assessments, Ritalin will continue with the previous dosage and Donepezil will reach 7.5 mg by week 6. In week 6, with a phone call the family is asked to report gastrointestinal problems or other symptoms. If no report of side effects was given, a dose of 10 mg is administered in weeks 7 and 8. Week 8: Patients refer in person. Drug side effects questionnaire and the Conners Parent Scale and General Clinical Assessment are filled and then CANTAB test is run.

**Category**

Treatment - Drugs

**2**

**Description**

The intervention group (2): After the initial evaluation (Connor's parent questionnaire, IQ test,CANTAB test) and gaining the consent of the children and their parents, Ritalin medication at 0.5 milligrams per kilogram of body weight begins. This dosage is divided into hours of 8 am, 12 am, and 4 pm. In addition to Ritalin, this group receive placebo. The content of placebo is Starch. Placebo pills in identical shape and size in the same package with Donepezil are prepared. At the end of week two, digestive problems and irritation or other complications are asked through a phone call to family. At week 4 patients refer to hospital in person. Drug side effects questionnaire and a Connor's parent questionnaire are asked to be filled, and then the CANTAB test is administered. In week 6, with a phone call the family is asked to report gastrointestinal problems or other symptoms. At week 8: patients refer in person. First, drug side effects questionnaire and a Connor's parent questionnaire are asked to be filled, and then the CANTAB test is administered.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Rozbeh Hospital

**Full name of responsible person**

Parisa Pakdel

**Street address**

Not far from the Qazvin Square, Sought Kargar Ave

**City**

Tehran

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Doctor Masood Yonesian

**Street address**

Central Organization of University, Ghods Ave, 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**

Vice chancellor for research, 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**

Tehran University of Medical Science

**Full name of responsible person**

Parisa Pakdel

**Position**

Fellow and Collaborative

**Other areas of specialty/work**

**Street address**

Rozbeh Hospital, not far from the Qazvin Square, Sought Kargar Ave.

**City**

Tehran

**Postal code**

**Phone**

+98 21 5541 9154

**Fax**

**Email**

p-pakdel@razi.tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Tehran Univercity of Medical Sciences
**Full name of responsible person**
Zahra Shahrivar
**Position**
Associate Professor.Fellowship
**Other areas of specialty/work**
**Street address**
Rozbeh Hospital. not far from the Gazvin Square. Sought Kargar Ave.
**City**
Tehran
**Postal code**
**Phone**
+98 21 5540 9495
**Fax**
**Email**
sharivar@sina.tums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Tehran University of Medical Science
**Full name of responsible person**
Parisa Pakdel
**Position**
Fellow
**Other areas of specialty/work**
**Street address**
Rozbeh Hospital. not far from the Square of Qazvin, Sought Kargar Ave.
**City**
Tehran
**Postal code**
**Phone**
+98 21 5541 9154
**Fax**
**Email**
p-pakdel@razi.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*