

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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 University 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