Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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

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Postal code
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Fax
Email
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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