Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Efficacy and complication of Duloxetine in attention deficeit –hyperactivity disorder (ADHD) and comparison with Ritalin

Protocol summary

Summary

The purpose of this double blind clinical trial is to compare efficacy and side effects of Duloxetine and Ritalin in ADHD patients. In this study, 40 patients in the age range of 11-18 with ADHD will be randomly assigned into intervention or control groups. The patients in the intervention group will receive Duloxetine and control group will receive Ritalin. CANERS test for parents (summarized and edited format) and ADHD rating scale for parents and teacher will be performed before treatment and after 2, 4, 6 and 8 weeks and side effect questionnaire will be administered in 2, 4, 6 and 8 weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110127462N2**
Registration date: **2011-10-19, 1390/07/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-10-19, 1390/07/27

Registrant information

Name

Mohammad Reza Mohammadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 3540

Email address

pprc@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and complication of Duloxetine in attention deficeit –hyperactivity disorder (ADHD) and comparison with Ritalin

Public title

Efficacy and complication of Duloxetine in attention deficeit –hyperactivity disorder (ADHD) and comparison with Ritalin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnostic criteria based on DSM IV for children with ADHD, age range 11-18, no consumption of any effective psychological drugs in past two week
Exclusion criteria: mental retardation, any other psychological disorders except for ODD, history of allergy to Duloxetine, serious medical conditions such as heart disease, uncontrolled convulsive disorder, systolic pressure upper than 125 mmhg or resting pulse less than 60 or more than 115 bit/m

Age

From **11 years** old to **18 years** old

Gender

Both

Phase
N/A
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
Tehran University of Medical Sciences
Street address
Qods street, Keshavarz Blvd, Tehran
City
Tehran
Postal code
Approval date
2011-06-12, 1390/03/22
Ethics committee reference number
11148

Health conditions studied

1

Description of health condition studied
attention deficiency hyperactivity disorder
ICD-10 code
F90.0
ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description
attention deficiency hyperactivity disorder
Timepoint
Baseline, 2, 4, 6, 8 weeks after treatment
Method of measurement
CANERS test for parents (summerized and edited format) and ADHD rating scale for parents and teacher

Secondary outcomes

1

Description
drugs side effects
Timepoint
Baseline, 2,4,6,8 weeks after treatment
Method of measurement
side effect questionnaire

Intervention groups

1

Description
Intervention group: Duloxetine 1/4 capsule in the first week, 1/2 capsule in second week, 3/4 capsule in third week and 1 capsule in fourth week
Category
Treatment - Drugs

2

Description
Control group: according to Ritalin dosage 0.4-1.3 mg/kg, Ritalin 1 capsule for the first week (1/2 in the morning and 1/2 at noon), 2 capsule for the second week (1 capsule in the morning and 1 capsule at noon); if the weight of patient is more than 30 kg, 3 capsule will be daily prescribed for the third week (1 capsule in the morning and 1 capsule at noon and 1 capsule in the afternoon)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatry and Psychology Research Center, Roozbeh Hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mrs Moamaie
Street address
Qods street, Keshavarz Blvd, Tehran
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

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

Psychiatry research center, Tehran University of Medical Sciences

Full name of responsible person

Rozita Jalilian

Position

MD student

Other areas of specialty/work

Street address

Psychiatry and Psychology Research Center, Roozbeh Hospital, South Kargar Avenue, after the Lashkar crossroads, Tehran, IRAN

City

Tehran

Postal code

Phone

+98 21 5541 3540

Fax

Email

rozita_jalilian@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Psychiatry and Psychology Research Center, Tehran University of Medical Sciences

Full name of responsible person

Mohammad Reza Mohammadi

Position

MD

Other areas of specialty/work

Street address

Psychiatry and Psychology Research Center, Roozbeh Hospital, South Kargar Avenue, after the Lashkar crossroads, Tehran, IRAN.

City

Tehran

Postal code

Phone

+98 21 5541 3540

Fax

Email

pprct@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Psychiatry and Psychology Research Center

Full name of responsible person

Maryam Salmanian

Position

MS/Researcher

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

pprct@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