Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Duloxetine in comparison with Methylphenidate in treatment of children with Attention Deficit/ Hyperactivity Disorder

Protocol summary

Summary

Goal of this study is comparison of Duloxetine with Methylphenidate in treatment of attention deficit - hyperactivity disorder. For this purpose, we will include 10 child aged 6-12 years old with attention deficit - hyperactivity disorder who refer to child and adolescent psychiatry clinic. Exclusion criteria is mental retardation and comorbidity of major psychiatric disorders. After written consent we will register their demographic characteristics and apply Kiddie Schedule for Affective Disorders and Schizophrenia-Present and Lifetime Version semi structured interview for diagnosis of attention deficit -hyperactivity disorder and comorbidities. In a 6 weeks open trial , we will prescribe Duloxetine or Methylphenidate to these patients . For evaluating effects of the drugs and their complications , we will use of attention deficit -hyperactivity disorder Rating Scale , Conners Scale-parent and side effect checklist form each two weeks . By Children Depression Inventory and Revised Children's Manifest Anxiety Scale we will compared depressive and anxiety symptoms in beginning and at the end of the trial

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101510363N2**
Registration date: **2012-11-08, 1391/08/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-11-08, 1391/08/18

Registrant information

Name

Nasrin Dodangi

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-09-20, 1392/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Duloxetine in comparison with Methylphenidate in treatment of children with Attention Deficit/ Hyperactivity Disorder

Public title

Comparison of Duloxetine and Methylphenidate in treatment of children with Attention Deficit/ Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : ADHD diagnosis according to DSM-IV-TR that is applied by two psychiatrists; age between 6-12 years old Exclusion criteria : mental retardation; history

of heart disease; drug sensitivity; comorbidity of severe mental illnesses such as bipolar disorder, major depressive disorder, conduct disorder, psychosis; history of seizure.

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation Sciences

Street address

Koodakyar st., Daneshgah st., Velenjak

City

Tehran

Postal code

Approval date

2012-07-24, 1391/05/03

Ethics committee reference number

7188/t/801/91

Health conditions studied

1

Description of health condition studied

Attention Deficit Hyperactivity Disorder(ADHD)

ICD-10 code

F90.0

ICD-10 code description

Attention deficit: disorder with hyperactivity hyperactivity disorder syndrome with hyperactivity

Primary outcomes

1

Description

severity of ADHD symtoms

Timepoint

each two weeks

Method of measurement

ADHD rating scale/ Conners rating scale-parent form

Secondary outcomes

1

Description

drug side effects, severity of depressive and anxiety symptoms

Timepoint

beginning and end of trial

Method of measurement

checklist of side effects- CDI-RCMAS

Intervention groups

1

Description

In Duloxetine group , we will prescribe this agent for 6 weeks once daily orally at night. The dose is 15 mg/d for the first week and 30 mg/d for the next 3 weeks. If needed , we will increase the dose to 60 mg/d in the last 2 weeks, and if not it will continue in the same dose.

Category

Treatment - Drugs

2

Description

In control group, Methylphenidate (Ritalin) will be given 1/2 BD in first week and TDS in second week orally (one in morning , one in afternoon and one at the evening). Then patients will evaluate and if needed , the dose will increase.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavan & Rofide clinic

Full name of responsible person

Nasrin Dodangi

Street address

Razi psychiatric hospital, Aminabad, Shahrerey

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Social Welfare and Rehabilitation Sciences
Full name of responsible person
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No.14; Shaghayegh alley; Roshanaei st.; Qeitarie
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
University of Social Welfare and Rehabilitation 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

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Web page address

Person responsible for updating data

Contact

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