# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 Jun 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)

**Phone**

+98 21 3340 1604

**Email address**

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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**
Nasrin Dodangi
**Street address**
No.14; Shaghayegh alley; Roshanaei st.; Qeitarie
**City**
Tehran
**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

**Contact**
**Name of organization / entity**
University of Social Welfare and Rehabilitation Sciences
**Full name of responsible person**
Nasrin Dodangi
**Position**
child and adolescent psychiatrist/ assistant professor
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## Person responsible for scientific inquiries

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## 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*