

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

An open trial of Duloxetine in the treatment of children with attention-deficit/hyperactivity disorder

Protocol summary

Summary

In this survey we want to investigate the effect of Duloxetine in treatment of children with attention deficit -hyperactivity disorder. First we will select 10 child aged 6-12 years old with attention deficit -hyperactivity disorder who refer to child and adolescent psychiatric clinic according to inclusion and exclusion criteria . After written consent we will register their demographic characteristics and 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 trial , we will prescribe Duloxetine in dose of 15 mg/d for the first week and 30 mg/d for next 3 weeks , then if needed we will increase the dose to 60 mg/d . For evaluating effects of the drug and its 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: **IRCT2012072210363N1**
Registration date: **2012-11-07, 1391/08/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-07, 1391/08/17

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

An open trial of Duloxetine in the treatment of children with attention-deficit/hyperactivity disorder

Public title

effect of Duloxetine in treatment of ADHD

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)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

7929/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 symptoms

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 this study we will prescribe Duloxetine daily at night for 6 weeks. The dose is 15 mg/d for first week, 30 mg/d for next 3 weeks and if needed 60 mg/d for the last two weeks .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavan & Rofide clinic, University of Social Welfare and Rehabilitation Sciences

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
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Full name of responsible person
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child and adolescent psychiatrist/ assistant professor
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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