

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Duloxetine vs Methylphenidate in adolescents with ADHD: A randomized trial

Protocol summary

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Summary

The goal of this trial is to examine the efficacy and safety of Duloxetine vs Methylphenidate in the treatment of adolescents with ADHD. 30 patients age between 11 to 18 years will be included. Participants will be randomly allocated to receive Duloxetine (30 mg/day and will be titrated up to 60 mg/day after a week) or Methylphenidate (10 mg/day and will be increased to 40 mg/day weekly according to the patient tolerance) for 6 weeks. Participants will be evaluated at baseline for ADHD symptom severity and every two weeks and the end of sixth week for ADHD symptom severity and drug side effects. Comorbidities will be assessed using K-SADS-PL semi-structured interview at the baseline.

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-12-01, 1388/09/10

Expected recruitment end date

2010-03-30, 1389/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810193029N1**

Registration date: **2010-03-01, 1388/12/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-03-01, 1388/12/10

Registrant information

Name

Javad Mahmoudi Gharai

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 9151

Email address

Scientific title

Duloxetine vs Methylphenidate in adolescents with ADHD: A randomized trial

Public title

Duloxetine in ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of ADHD according to DSM-IV-TR Criteria, age range of 11 to 18 years Exclusion criteria: Presence of mental retardation, cardiac problems, known contraindications to study drugs, Comorbidity of severe major depression, conduct disorder, bipolar or psychotic disorders, epilepsy taking anticonvulsants at the time of enrollment and during the trial, pregnancy or lactation, refusal to participate

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 and Health Services

Street address

Qods Ave, Keshavarz Blvd.

City

Tehran

Postal code

Approval date

2009-12-01, 1388/09/10

Ethics committee reference number

88-02-30-8700

Health conditions studied

1

Description of health condition studied

ADHD

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

ADHD severity of symptoms

Timepoint

Baseline, Every 2 weeks, End point

Method of measurement

Conner's and ADHD rating Scale

Secondary outcomes

1

Description

Drug side effects

Timepoint

every 2 weeks and end point

Method of measurement

Questionnaire

Intervention groups

1

Description

Duloxetine, 30-60 mg/day, starting dose 30 mg/day for 1 week and 60 mg/day for the following 5 weeks

Category

Treatment - Drugs

2

Description

Methylphenidate, starting dose: 10 mg/ day divided in two doses for 1 week and 20, 30 and 40 mg/day divided in 3 doses in weeks 2, 3 and 4 respectively according to the patient tolerance and continue in weeks 5 and 6

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Center

Full name of responsible person

Javad Mahmoudi Gharaei

Street address

Dr Gharib Ave

City

Tehran

2

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Javad Mahmoudi-Gharaei

Street address

South Kargar Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences and Health services

Full name of responsible person

Mrs, Khalili

Street address

Qods 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

Tehran University of Medical Sciences and Health services

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 Sciences

Full name of responsible person

Dr. Javad Mahmoudi-Gharaei

Position

Child and Adolescent Psychiatrist

Other areas of specialty/work

Street address

Psychiatry and Psychology research Center, Roozbeh Hospital, South Kargar Ave.,

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Javad Mahmoudi-Gharaei

Position

Assistant professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences and Health Services

Full name of responsible person

Dr. Javad Mahmoudi-Gharaei

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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