Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Duloxetine vs Methylphenidate in adolescents with ADHD: A randomized trial

Protocol summary

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.

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
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Iran (Islamic Republic of)
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+98 21 5541 9151
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jmahmoudi@razi.tums.ac.ir

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

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
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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