Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A double-blind, placebo-controlled study on the efficacy of risperidone adjunctive to methylphenidate in patients with ADHD

Protocol summary

Summary

This is a randomized, double-blind clinical trial to evaluate the efficacy of add on Risperidone to methylphenidate in ADHD. In this study 80 patients, referred to psychiatry ward of Farshchian Hospital will be enrolled in the study with consent inform ,who have been diagnosed as ADHD based on DSM-IV TR and Conner's rating scale ,their age is between 6 to 12years with IQ> 70 and have no known systemic or psychiatric disease . The patients will be divided into two groups based on randomized blocks. The case group will receive methylphenidate with maximum dose of 30 mg per day with risperidone witn maximum dose of 1 mg per day and the control group will receive methylphenidate with maximum dose of 30 mg per day along with placebo for 8 weeks. Prior to start the treatment, they will undergo ALT, AST, LDH, CPK, LDL, HDL, CHOL, and TG tests. Before the treatment and the intervals of 2,4,6and 8weeks after the treatment, the patients wiil be assessed through Conner's rating Scale and Clinical Global Rating scale and finally the improvement rate of the both groups compared to each other. .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211051743N10**
Registration date: **2013-01-26, 1391/11/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-01-26, 1391/11/07

Registrant information

Name

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Name of organization / entity

Research Center for Behavioral Disorders and Substance Abuse, Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research center for behavioral disorders and substance abuse, Hamadan University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double-blind, placebo-controlled study on the efficacy of risperidone adjunctive to methylphenidate in patients with ADHD

Public title

efficacy of risperidone in ADHD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Diagnosed as ADHD according to DSM-IV TR and conner's scale; Age between 6 to12years; No other psychiatric disorders along with ADHD; No other

debilitating physical illness along with ADHD; IQ>70 Exclusion Criteria: Severe drug complication during the study; abnormal labratory tests (BC,NA,K,BS,BUN,CR,TSH,AST,ALT,PRL,TOT CHOL,LDL CHOL,HDL,CHOL,TG).

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: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamadan University of Medical Sciences

Street address
Farshchian Hospital

City
Hamadan

Postal code

Approval date
2012-09-22, 1391/07/01

Ethics committee reference number
2552-9-35-16-د-پ

Health conditions studied

1

Description of health condition studied
attention deficit/hyperactivity disorder

ICD-10 code
F90.0

ICD-10 code description
Disturbance of activity and attention

Primary outcomes

1

Description
improvement ADHD symptoms

Timepoint
first of the study and after 2nd,4th,6th and 8th week of the study.

Method of measurement
Clinical Global Impression Scale and conner`s parents rating scale for ADHD

Secondary outcomes

1

Description
drug side effects

Timepoint
after 2nd,4th,6th and 8th week of the study

Method of measurement
Clinical Global Impression Scale

Intervention groups

1

Description
methylphenudate with maximum dose of 30 mg per day and placebo for 8 weeks

Category
Treatment - Drugs

2

Description
methylphenudate with maximum dose of 30 mg per day and risperidone with maximum dose of 1 mg per day for 8 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Hospital

Full name of responsible person
shahrokh akbarian

Street address
Farshchian Hospital

City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research center for behavioral disorders and substance abuse, Hamadan University of Medical Science
Full name of responsible person
dr.mohammad Ahmadpanah
Street address
Farshchian Hospital
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research center for behavioral disorders and substance abuse, Hamadan University of Medical Science
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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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