

# 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 with 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 will 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

Mohammad Haghghi

##### Name of organization / entity

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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1827 4184

##### Email address

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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 laboratory 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-پ-د

## 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**

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

**Full name of responsible person**

shahrokh akbarian

**Position**

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Farshchian Hospital

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**Postal code****Phone**

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### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Research center for behavioral disorders and substance abuse, Hamadan university of medical sciences

**Full name of responsible person**

Dr. Leila Jahangard

**Position**

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### Person responsible for updating data

**Contact****Name of organization / entity**

Research center for behavioral disorders and substance abuse, Hamadan university of medical sciences

**Full name of responsible person**

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**Position**

Resident of psychiatry

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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*