

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The effect of lavender medicine as a supplementary drug in the treatment of children with attention deficit hyperactivity disorder

#### Protocol summary

##### Summary

This is a double blinded, randomized, clinical trial, the aim of this study is evaluating the efficacy of Lavender as an adjuvant therapy along with methylphenidate on the treatment of children with attention deficit hyperactivity disorder (ADHD). Inclusion criteria: Patients with ADHD, age between 6 to 12 years. exclusion criteria: The patients with severe complications; People who do not have the consent to participate in the study; do not follow up. The total sample size is 44 and patients are randomly divided into two parallel groups as intervention and placebo groups. Also the randomization is doing with a randomization software. The intervention group is under treatment with methylphenidate and lavender and the placebo group is under treatment with methylphenidate. After 8 weeks, the outcomes of treatment are assessed using a ADHD Rating Scale-IV. Also the doctors and patients are blinded about study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017091612782N18**

Registration date: **2017-10-15, 1396/07/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-15, 1396/07/23

##### Registrant information

##### Name

Ali Mehrabi kushki

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3629 1510

##### Email address

mehrabi@mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice President of Research, School of Medicine, Isfahan University of Medical Sciences

##### Expected recruitment start date

2016-03-19, 1394/12/29

##### Expected recruitment end date

2017-03-20, 1395/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of lavender medicine as a supplementary drug in the treatment of children with attention deficit hyperactivity disorder

##### Public title

The effect of lavender on the treatment of children with attention deficit hyperactivity disorder

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with attention deficit hyperactivity disorder (ADHD), age between 6 to 12 years. exclusion criteria: The patients with severe complications; People who do not have the consent to participate in the study; do not follow up.

##### 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: **44**

**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**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Isfahan, Iran.

**City**

Isfahan

**Postal code**

7346181746

**Approval date**

2010-09-23, 1389/07/01

**Ethics committee reference number**

IR.MUI.REC.1395.30295

## Health conditions studied

### 1

**Description of health condition studied**

Attention-Deficit/Hyperactivity Disorder(ADHD)

**ICD-10 code**

F90.0

**ICD-10 code description**

Disturbance of activity and attention

## Primary outcomes

### 1

**Description**

Recovery rate

**Timepoint**

Before intervention and 8 weeks after intervention

## Method of measurement

ADHD Rating Scale-IV

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Patients under treatment with methylphenidate tablet and lavender

**Category**

Treatment - Drugs

### 2

**Description**

Control group: Patients under treatment with methylphenidate tablet and placebo (starch and lactose content)

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Khorshid Hospital

**Full name of responsible person**

Fereshteh Shakibaei

**Street address**

Khorshid Hospital, Isfahan, Iran.

**City**

Isfahan

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Mansour Siavash

**Street address**

Isfahan University of Medical Sciences, Isfahan, Iran.

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Isfahan University of Medical 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

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**Web page address****Person responsible for general inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Fereshteh Shakibaei

**Position**

Psychologist/ Associate professor

**Other areas of specialty/work****Street address**

Isfahan University of Medical Sciences, Isfahan, Iran.

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shakibaei@med.mui.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Isfahan University of Medical Sciences.

**Full name of responsible person**

Ali Mehrabi Koushki

**Position**

Responsible for research/Master of Science

**Other areas of specialty/work****Street address**

Research office , Al-Zahra hospital, Al-zahra street,  
Isfahan, Iran

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of medical sciences

**Full name of responsible person**

Mehdi Kahkeshani

**Position**

General practitioner

**Other areas of specialty/work****Street address**

Isfahan University of Medical Sciences, Isfahan, Iran.

**City****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