# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jul 2026

## Comparison of Methylphenidate with the Combanition of Methylphenidate (MPH) and Crocus sativus (Saffron) in the treatment of children and adolescents with Attention-Deficit Hyperactivity Disorder (ADHD): a Randomized, Double Blind Clinical Trial

## Protocol summary

**Study aim**

The main aim of this study is comparison of Methylphenidate (MPH) with the combanition of Methylphenidate and Crocus sativus (Saffron) in the treatment of Attention-Deficit Hyperactivity Disorder (ADHD).

**Design**

A randomized, double -blind, with parallel groups clinical trial. 90 patients with Attention-Deficit- Hyperactivity Disorder in two groups of 45 people in a phase III trial are assigned randomly.

**Settings and conduct**

Location is Fetros Comprehensive Health Center.90 patients are selected. 45 patients in Methylphenadiate group and 45 patients in combined Methylphenadiate and saffron group are assigned randomly. In this double-blind study, the psychiatrist and data analyser were kept blind to the treatment. In fact, participants pick up envelopes inside the box randomly which are in an unspecified wrapper.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Diagnosis of attention-deficit-hyperactivity disorder based on diagnostic and Statistical Manual of Mental Disorders (DSM), Lack of mental retardation, No use of Methylphenidate and Crocus sativus (saffron) before the study. Exclusion criteria:Parent's dissatisfaction to participate in study, Psychiatric comorbidities (except for oppositional defiant disorder), Drug allergy.

**Intervention groups**

The first intervention group: group under treatment of Methylphenidate. The second intervention group: group under treatment of combined MPH and Saffron. The first group for 8 weeks uses10 -30 mg/d of Methylphenidate tablet (Created by Poorsina Pharmaceutical Company) depended on their weights daily . Also, the second group received previous prescription with Saffron capsules (Created by Knowledge-based company "Pouyesh darooye Sina") at a dose of 20–30 mg/d depending on their weight.

**Main outcome variables**

Symptoms of hyperactivity, symptoms of attention deficit, impulsivity

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20190602043790N2**
Registration date: **2020-06-27, 1399/04/07**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-27, 1399/04/07**
Update count: **0**

**Registration date**

2020-06-27, 1399/04/07

**Registrant information**

**Name**
Saba Hasanvandi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 66 3324 2643
**Email address**
s.hasanvandi@alzahra.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-06-21, 1399/04/01
**Expected recruitment end date**
2020-07-22, 1399/05/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of Methylphenidate with the Combanition of Methylphenidate (MPH) and Crocus sativus (Saffron) in the treatment of children and adolescents with Attention-Deficit Hyperactivity Disorder (ADHD): a Randomized, Double Blind Clinical Trial

**Public title**
Comparison of Methylphenidate with the Combanition of Methylphenidate with Crocus sativus ( saffron) in the treatment of ADHD
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Diagnosis of attention-deficit-hyperactivity disorder based on diagnostic and Statistical Manual of Mental Disorders (DSM) Lack of mental retardation No use of Methylphenidate and Crocus sativus (saffron) before the study
**Exclusion criteria:**
Parent's dissatisfaction to participate in study Psychiatric comorbidities (except for oppositional defiant disorder) Drug allergy
**Age**
From **6 years** old to **16 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Care provider
- Data analyser

**Sample size**
Target sample size: **90**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The randomization method is a simple randomization method. The unit of randomization is individual. Using the table of random numbers, patients are randomly divided into two groups: Methylphenidate or a combination of Methylphenidate and Saffron. Even numbers are considered for the Methylphenidate group and odd numbers are for the Methylphenidate and Saffron group. Random allocation is done by the researcher and the clinical caregiver and data analyzer are not aware of the allocation of patients.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Treatment allocation was concealed from the psychiatrist and the data analyser who rated patients by using successively numbered, opaque, and sealed envelopes. In fact, participants pick up envelopes inside the box randomly which are in an unspecified wrapper. They are aware which experimental group they were assigned to.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Lorestan University of Medical Sciences
**Street address**
Kilometer 5 Road of Tehran-Khorram Abad, Lorestan University of Medical Sciences, Khorram Abad
**City**
Khorram Abad
**Province**
Lorestan
**Postal code**
44316-68151
**Approval date**
2019-12-18, 1398/09/27
**Ethics committee reference number**
IR.LUMS.REC.1398.227

## Health conditions studied

### 1

**Description of health condition studied**
Attention-Deficit Hyperactivity Disorder
**ICD-10 code**
F90.9
**ICD-10 code description**
Attention-deficit hyperactivity disorder, unspecified type

## Primary outcomes

### 1

**Description**
Hyperactivity symptoms
**Timepoint**
At the first of study (before the intervention), 4 and 8 week after starting taking Methylphenidate in first group and combined Methylphenidate with Saffron in second group, Attention-Deficit Hyperactivity symptoms are evaluated.

**Method of measurement**
Parent and Teacher Rating of Attention Deficit/Hyperactivity Disorder (ADHD-RS-IV)

**2**

**Description**
Attention-Deficit symptoms
**Timepoint**
At the first of study (before the intervention), 4 and 8 week after starting taking Methylphenidate in first group and combined Methylphenidate with Saffron in second group, Attention-Deficit Hyperactivity symptoms are evaluated.
**Method of measurement**
Parent and Teacher Rating of Attention Deficit/Hyperactivity Disorder (ADHD-RS-IV)

**3**

**Description**
Impulsivity
**Timepoint**
At the first of study (before the intervention), 4 and 8 week after starting taking Methylphenidate in first group and combined Methylphenidate with Saffron in second group, Attention-Deficit Hyperactivity symptoms are evaluated.
**Method of measurement**
Parent and Teacher Rating of Attention Deficit/Hyperactivity Disorder (ADHD-RS-IV)

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group 1:The first group was treated with (MPH): The first group for 8 weeks uses10 -30 mg/d of Methylphenidate tablet (Created by Poorsina Pharmaceutical Company) depended on their weights daily .
**Category**
Treatment - Drugs

**2**

**Description**
intervention group 2: The second group received 10 -30 mg/d of Methylphenidate tablet with Saffron capsules (Created by Knowledge-based company "Pouyesh darooye Sina") for 8 weeks at a dose of 20–30 mg/d depending on their weight daily.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Fetros Urban Comprehensive Center
**Full name of responsible person**
Amin Shoja
**Street address**
Delfani Street, Enghelab Street, Khorram abad, Lorestan, Iran.
**City**
Khorram Abad
**Province**
Lorestan
**Postal code**
6813954833
**Phone**
+98 66 3321 4550
**Fax**
**Email**
Amin.shoja@lums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Khoram-Abad University of Medical Sciences
**Full name of responsible person**
Dr Ebrahim Fallahi
**Street address**
Kilometer 5 Road Tehran- Khorram Abad, Lorestan University of Medical Sciences, Khorram Abad, Lorestan.
**City**
Khorram Abad
**Province**
Lorestan
**Postal code**
44316-68151
**Phone**
+98 66 3312 0157
**Email**
falahi.e@lums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Khoram-Abad University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
Public
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**
Khoram-Abad University of Medical Sciences

**Full name of responsible person**
Saba Hasanvandi

**Position**
Assistant professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Psychology

**Street address**
Lorestan University of Medical Sciences, Kilometer 5 Road of Tehran-Khorram Abad, Khorram Abad, Lorestan, Iran.

**City**
khorram Abad

**Province**
Lorestan

**Postal code**
6813833946

**Phone**
+98 66 3324 2643

**Email**
s.hasanvandi@alzahra.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Khoram-Abad University of Medical Sciences

**Full name of responsible person**
Saba Hasanvandi

**Position**
Assistant professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Psychiatrics

**Street address**
Kilometer 5 Road of Tehran-Khorram Abad, Lorestan University of Medical Sciences, Khorram Abad, Lorestan, Iran.

**City**
khorram Abad

**Province**
Lorestan

**Postal code**
6813833946

**Phone**
+98 66 3330 0661

**Fax**

**Email**
s.hasanvandi@alzahra.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Khoram-Abad University of Medical Sciences

**Full name of responsible person**
Saba Hasanvandi

**Position**
Assistant professor

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Psychology

**Street address**
Kilometer 5 Road of Tehran-Khorram Abad, Lorestan University of Medical Sciences, Khorram Abad, Lorestan, Iran.

**City**
khorram Abad

**Province**
Lorestan

**Postal code**
6813833946

**Phone**
+98 66333006615

**Fax**
+98 66 3330 0661

**Email**
s.hasanvandi@alzahra.ac.ir

**Web page address**
http://lums.ac.ir/index.php?module=cdk&func=loadmodule&system=cdk&sismodule=user/content_view.php&cnt_id=11534&ctp_id=17&id=1770&sisOp=view

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available

**Title and more details about the data/document**
Only part of the data, such as information related to main outcome or like that , can be share.

**When the data will become available and for how long**
Start of access, 6 months after publishing the results

**To whom data/document is available**
Only people working in academic institutions could apply.

**Under which criteria data/document could be used**
People who are conducting clinical trials in this field could apply.

**From where data/document is obtainable**
By referring to the electronic address: s.hasanvandi@alzahra.ac.ir

**What processes are involved for a request to access data/document**

The applicant can receive information by registering the exact personal details.

**Comments**