Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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

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Saba Hasanvandi
Name of organization / entity
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Iran (Islamic Republic of)
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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
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Delfani Street, Enghelab Street, Khorram abad, Lorestan, Iran.
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
Dr Ebrahim Fallahi
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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

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Person responsible for updating data

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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