

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Investigating the effect of Violet syrup as an subsidiary treatment for insomnia in patients with attention deficit hyperactivity disorder treated with Ritalin. In a double-blind clinical trial study in children 6-12 years

#### Protocol summary

##### Study aim

Determining the effect of violet syrup as an adjunctive treatment in the treatment of insomnia caused by Ritalin in patients with attention deficit hyperactivity disorder (ADHD).

##### Design

Clinical trial with control group with parallel groups, double-blind, randomized on 60 patients, NCSS software and random block method are used to randomize the study.

##### Settings and conduct

60 patients with ADHD who went to Imam Clinic Rezai Shiraz have applied and will be included in the study. Demographic information will be recorded. Then these people will be randomly divided into groups A and B and they will be introduced to the pharmacist with two codes A and B, one of these codes (bottle) contains violet syrup and the other one contains placebo, and the shape and The size of the bottles are completely the same and only the pharmacist knows about their contents, and both the researcher and the patient are unaware of the contents inside the bottle. (for double-blindness of the study) the therapeutic dose of Banafshe syrup is determined as 5 cc twice a day, half an hour before meals.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Having DSM 5 diagnostic criteria for ADHD 2 - Age 6 to 12 years Exclusion criteria: 1- Existence of a serious medical disease such as heart disease 2- Uncontrolled seizure disorder 3- Weight below 13.5 kg

##### Intervention groups

Drug group patients take Ritalin tablets with a daily dose of 1.5 to 3 mg per kilogram of body weight along with violet syrup in the amount of 5 cc twice a day. The placebo group of patients receives daily Ritalin tablets with a daily dose of 1.5 to 3 mg per kilogram of body weight along with Placebo syrup.

#### Main outcome variables

The score of children's sleep habits questionnai

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230930059556N1**

Registration date: **2024-02-13, 1402/11/24**

Registration timing: **retrospective**

Last update: **2024-02-13, 1402/11/24**

Update count: **0**

##### Registration date

2024-02-13, 1402/11/24

##### Registrant information

##### Name

Kimia Sazaiee

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3228 7237

##### Email address

kemeaszaei@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-22, 1401/09/01

##### Expected recruitment end date

2023-09-21, 1402/06/30

##### Actual recruitment start date

2022-11-22, 1401/09/01

##### Actual recruitment end date

2023-09-21, 1402/06/30  
**Trial completion date**  
2023-11-21, 1402/08/30

### Scientific title

Investigating the effect of Violet syrup as an subsidiary treatment for insomnia in patients with attention deficit hyperactivity disorder treated with Ritalin. In a double-blind clinical trial study in children 6-12 years

### Public title

Investigating the effect of Violet syrup as an subsidiary treatment for insomnia in children with attention deficit hyperactivity disorder

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Having DSM 5 diagnostic criteria for ADHD Age 6 to 12 years Not taking any medication affecting the mental state at least 2 weeks before the research

#### Exclusion criteria:

Mental retardation The presence of any psychiatric disorder except OCD History of allergy to the drugs used in the study Having a serious medical illness such as heart disease Uncontrolled seizure disorder People who have systolic blood pressure above 125 mm Hg or their resting pulse is less than 60 or more than 115 beats per minute. Weight under 5 13 kg

### Age

From **6 years** old to **12 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

### Sample size

Target sample size: **60**

Actual sample size reached: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The researcher enrolled the participants based on the convenience sampling method he does. From NCSS software (Number Cruncher statistical system) and Randomized block method is used to randomize the study. At Randomized block method, participants in 6 blocks (, AABB, ABAB BBAA, BABA, ABBA, BAAB) are classified as each block Includes 4 participants. In this study, "A" belongs to the drug group and "B". It is assigned to the placebo group, for example: in the block ", "ABAB The first person enters the drug group, the second person enters the placebo group, the third One entered the drug group and the fourth entered the placebo group. So , All eligible participants were

randomized to one of the arms The study is selected according to the random list.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The patients' doctors and drug providers will be blinded to the intervention allocation. It should be noted that the drug container is the same. And the intervention in the two groups are similar in terms of shape, color and method of use.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

##### Street address

Zand Ave, Shiraz University Of Medical Sciences

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814336

#### Approval date

2022-10-28, 1401/08/06

#### Ethics committee reference number

IR.SUMS.MED.REC.1401.161

## Health conditions studied

### 1

#### Description of health condition studied

Attention deficit hyperactivity disorder

#### ICD-10 code

F90

#### ICD-10 code description

Attention-deficit hyperactivity disorders

## Primary outcomes

### 1

#### Description

Sleep score based on Child Sleep Habits Questionnaire (CSHQ)

#### Timepoint

At the beginning of the study (before the intervention) and 4 and 8 weeks after starting to take the drug or

placebo

### Method of measurement

Children's sleep habits questionnaire

## Secondary outcomes

### 1

#### Description

Possible side effects of violet syrup

#### Timepoint

At any time of study

#### Method of measurement

Patient statement and clinical examination

## Intervention groups

### 1

#### Description

Intervention group: In 30 patients with attention deficit hyperactivity disorder aged 6 to 12 years who are treated with Ritalin, Banafshe syrup of Kimiagar company is prescribed with a dose of 5 cc twice a day.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The people of this group are prescribed placebo syrup with a dose of 5 cc 2 times a day for 8 weeks, which is made by the project's pharmacist at the Faculty of Pharmacy of Shiraz University.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza clinic

##### Full name of responsible person

Sara dehbozorgi

##### Street address

Namazi square

##### City

Shiraz

##### Province

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##### Postal code

7654971466

##### Phone

+98 917 716 9547

##### Email

dehbozorgi\_s@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Sara dehbozorgi

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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

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Sara dehbozorgi

##### Position

Assistant Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Psychiatrics

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## Person responsible for scientific inquiries

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Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available