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
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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

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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

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Sponsors / Funding sources

1

Sponsor

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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

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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