

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

A comparative study of the effectiveness of adding melatonin and sleep hygiene education to the usual treatment (pharmacological and non-pharmacological treatment) in reducing the symptoms of attention deficit hyperactivity disorder in adolescents with attention deficit hyperactivity disorder and sleep phase delay syndrome.

Protocol summary

Study aim

A comparative study of the effectiveness of adding melatonin and sleep hygiene education to the usual treatment (pharmacological and non-pharmacological treatment) in reducing the symptoms of attention deficit hyperactivity disorder in adolescents with attention deficit hyperactivity disorder and sleep phase delay syndrome.

Design

A clinical trial with a randomized control group of 75 patients

Settings and conduct

The study is conducted in psychiatric clinics and on teenagers aged 12 to 18 with attention deficit hyperactivity disorder. Children in two groups will be given medicine and sleep hygiene education. Questionnaires will be filled out before, during, and after the study.

Participants/Inclusion and exclusion criteria

1. Definitive diagnosis of ADHD with DSPS 2. Age range: between 12 and 18 years 3. Informed consent to participate in the research project 4. Having minimum education (reading and writing literacy) parents for sleep training for teenagers 1. Suffering from a chronic disease physical, including diabetes, liver problems, immune system defects, and autoimmune diseases 2. Presence of major psychiatric disorders such as bipolar disorder 3. Taking medicine with side effects of sleep problems such as insomnia or hypersomnia

Intervention groups

Group 1: For each patient, 3 mg of melatonin is added to his routine treatment. This group is treated with melatonin for 5 weeks. Group 2: This educational program as a psychoeducational program includes 5

sessions of 50 minutes.

Main outcome variables

Reducing symptoms of attention deficit hyperactivity disorder

General information

Reason for update

Acronym

ADHD

IRCT registration information

IRCT registration number: **IRCT20211004052670N5**

Registration date: **2023-11-13, 1402/08/22**

Registration timing: **prospective**

Last update: **2023-11-13, 1402/08/22**

Update count: **0**

Registration date

2023-11-13, 1402/08/22

Registrant information

Name

afsaneh karbasi amel

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01
Expected recruitment end date
2024-06-21, 1403/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

A comparative study of the effectiveness of adding melatonin and sleep hygiene education to the usual treatment (pharmacological and non-pharmacological treatment) in reducing the symptoms of attention deficit hyperactivity disorder in adolescents with attention deficit hyperactivity disorder and sleep phase delay syndrome.

Public title

Effectiveness of adding melatonin and sleep hygiene education to the usual treatment of attention deficit hyperactivity disorder with sleep phase delay syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of ADHD with DSPS between 12 and 18 years Informed consent to participate in the research project Having minimum education (reading and writing literacy) of parents for sleep training for teenagers

Exclusion criteria:

Suffering from chronic physical diseases including diabetes, liver problems, immune system defects and autoimmune diseases Taking medicine with side effects of sleep problems such as insomnia or hypersomnia

Age

From **12 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample in this research consists of 75 adolescents with ADHD and sleep phase delay syndrome with the opinion of a specialist in pediatric psychiatry based on the fifth edition of the Diagnostic and Statistical Manual of Psychiatric Disorders, who are selected by available sampling. Then on 25 leaves letter A, 25 leaves letter B, and 25 leaves letter C are written and each is placed in an envelope. Then each patient is asked to choose one envelope from among the envelopes. According to the selected envelope, the patient will be allocated to one of the three groups. The size of each group is 25 people and the waiting list is also 25 people.

Blinding (investigator's opinion)

Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences

Street address

Ibn Sina Street, Amin Hospital

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Isfahan

Postal code

8148653141

Approval date

2023-07-12, 1402/04/21

Ethics committee reference number

IR.MUI.MED.REC.1402.166

Health conditions studied

1

Description of health condition studied

Attention Deficit-Hyperactivity Disorder

ICD-10 code

F90.2

ICD-10 code description

Attention-deficit hyperactivity disorder, combined type

Primary outcomes

1

Description

Determining the mean scores of Conners Hyperactivity Questionnaire

Timepoint

The questionnaire is administered at the baseline visit (before the intervention), after participating in sleep health education sessions and taking melatonin medicine, and then three months after the intervention is completed for follow-up.

Method of measurement

Conners Hyperactivity Questionnaire

Secondary outcomes

1

Description

Sleep quality score

Timepoint

The questionnaire is administered at the baseline visit (before the intervention), after the training sessions on sleep hygiene and the use of melatonin medication, and three months after the end of the intervention for follow-up.

Method of measurement

Petersburg Sleep Quality Questionnaire

Intervention groups

1

Description

Intervention group 1: For each patient, 3 mg of melatonin is added to his routine treatment. The chemical structure of this drug is similar to serotonin. It has a fast and complete oral absorption and reaches the plasma peak within an hour, so it is used for people with sleep delay problems. In this group, patients are first given a checklist of drug side effects, and the checklist is checked during three visits. This group is treated with melatonin for 5 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: This educational program as a psychoeducational program includes 5 50-minute sessions that are conducted by a psychologist for parents of teenagers in a group and during 5 consecutive days. The first session: In this session, how teenagers are deprived of enough sleep to Parents are explained. The second session: why teenagers are so affected by lack of sleep. In other words, the causes and factors of sleep deprivation are taught to parents in this section. The third session: The consequences of sleep deprivation in teenagers are taught to parents. The fourth and fifth sessions: How can you help teenagers get enough sleep. In these two sessions, parents are taught various effective methods to help teenagers improve their sleep quality and quantity.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

Karbasi Amel Afsaneh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

غلامرضا عسگری

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Afsaneh Karbasi Amel

Position

Assistant Professor of Child and Adolescent Psychiatry

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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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