

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Ritalin with and without Melatonin on the quality of sleep and the severity of clinical symptoms in children with attention deficit hyperactivity disorder: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of Ritalin with and without Melatonin on the quality of sleep and the severity of clinical symptoms in children with attention deficit hyperactivity disorder

Design

This is a randomized clinical trial, phase II, in which 48 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible children with attention deficit hyperactivity disorder who will refer to Besat Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 5 to 10 years; Attention deficit hyperactivity disorder; Sleep disorder
Exclusion criteria: Phenylketonuria; Depression; Mental retardation; Using hypnotic drugs

Intervention groups

Intervention group: Tablet Ritalin 5 mg to 40 mg daily for one month plus tablet Melatonin 3 mg once a night for 10 days
Control group: Tablet Ritalin 5 mg to 40 mg daily for one month

Main outcome variables

Primary outcome: Assessing the sleep quality
Assessing the severity of clinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N235**
Registration date: **2018-09-22, 1397/06/31**
Registration timing: **retrospective**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-01, 1396/09/10

Expected recruitment end date

2018-07-11, 1397/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ritalin with and without Melatonin on the quality of sleep and the severity of clinical symptoms in children with attention deficit hyperactivity disorder: a randomized clinical trial

Public title

Effect of Ritalin with and without Melatonin on the quality

of sleep and the severity of clinical symptoms in children with attention deficit hyperactivity disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 5 to 10 years; Attention deficit hyperactivity disorder; Sleep disorder

Exclusion criteria:

Phenylketonuria; Depression; Mental retardation; Using hypnotic drugs

Age

From **5 years** old to **10 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

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Province

Hamadan

Postal code

6517838695

Approval date

2017-11-27, 1396/09/06

Ethics committee reference number

IR.UMSHA.REC.1396.581

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

Assessing the sleep quality

Timepoint

At baseline and then one and two months after intervention

Method of measurement

Using children sleep habit questionnaire (CSHQ)

2

Description

Assessing the severity of clinical symptoms

Timepoint

At baseline and then one and two months after intervention

Method of measurement

Using Conner questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Tablet Ritalin 5 mg to 40 mg daily for one month plus tablet Melatonin 3 mg once a night for 10 days

Category

Treatment - Drugs

2

Description

Control group: Tablet Ritalin 5 mg to 40 mg daily for one month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

to Besat Hospital

Full name of responsible person

Ghazal Sami

Street address

Besat Hospital, Shahed Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Ghazal Sami

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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