

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Melatonin Effects on Sleep Patterns, Symptoms of Hyperactivity and Attention Deficiency in Ritalin Treated Children with Attention Deficit Hyperactivity Disorder: A Randomized Double Blind Clinical Trial

Protocol summary

Summary

The objective of this study is evaluating melatonin effects on sleep patterns, symptoms of hyperactivity and attention deficiency in ritalin treated children with attention deficit hyperactivity disorder. forty four children referring to private psychology clinic at the age range of 7-12 who meet the inclusion criteria will divide in to two groups in a double blind permuted block randomized allocation design based on gender blocks. One group taking melatonin (3or6mg based on weight: 3mg in children under 30kg and 6mg in children above 30kg according to Kristiaan and colleagues (KRISTIAAN, HEIJDEN et al. 2007) combined with Ritalin (1mg/kg), and the other group taking placebo combined with Ritalin (1mg/kg). In the first visit, personal and demographic questionnaires, special tests for ADHD (based on diagnostic criteria for DSM-IV) such as ADHD Rating Scale, SDSC (Sleep Disturbance Scale for Children) sleep questionnaire will complete by mothers; and then, anthropometric measurements in standard situation will perform. ADHD rating scale and SDSC sleep questionnaires will complete by mothers at baseline, and will repeat at 2, 4, and 8 weeks after the treatment. Anthropometric assessments will done at baseline and will repeat 8 weeks after the treatment. At the end of study, the stimulant drug side effects questionnaire will complete by mothers; then, the side effects will compare between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203167462N4**

Registration date: **2012-03-17, 1390/12/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-17, 1390/12/27

Registrant information

Name

Mohammad Reza Mohammadi

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-03-17, 1390/12/27

Expected recruitment end date

2012-06-05, 1391/03/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Melatonin Effects on Sleep Patterns, Symptoms of Hyperactivity and Attention Deficiency in Ritalin Treated Children with Attention Deficit Hyperactivity Disorder: A Randomized Double Blind Clinical Trial

Public title

Melatonin Effects in Ritalin Treated Children with Attention Deficit Hyperactivity Disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age range of 7-12; ADHD combined form; Clinical need to treat with Methylphenidate; parental consent and child ascent Exclusion criteria: any confounding co-morbidity; any drug supplements or narcotics consumption; Children with history of major prenatal complications such as prematurity, low birth weight (reported by parents), any past or present psychosis, comorbid tourette syndrome, celiac, phenylketonuria, autism, or other persistent developmental disorders

Age

From **7 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Research Deputy of Tehran University of Medical Sciences, Keshavarz Avenue, Tehran. Iran

City

Tehran

Postal code

Approval date

2011-04-16, 1390/01/27

Ethics committee reference number

31807

Health conditions studied

1

Description of health condition studied

Attention Deficit Hyperactivity Disorder (ADHD)

ICD-10 code

F90.0

ICD-10 code description

Disturbance of activity and attention

Primary outcomes

1

Description

Sleep disorders score

Timepoint

0-2-4-8 weeks

Method of measurement

Sleep disorders scale for children (SDSC)

2

Description

Appetite score

Timepoint

0-2-4-8 weeks

Method of measurement

Standard appetite questionnaire for children

3

Description

Attention deficiency score and Hyperactivity score

Timepoint

0-2-4-8 weeks

Method of measurement

ADHD rating scale for children (completed by parents)

Secondary outcomes

1

Description

Stimulants side effects

Timepoint

week 8

Method of measurement

Stimulants side effects questionnaire

Intervention groups

1

Description

Control: Methylphenidate (Ritalin: 1mg/kg) combined with Placebo taking 1 hour before bed time

Category

Treatment - Drugs

2

Description

Intervention group: Methy phenidate (Ritlin: 1mg/kg) combined with Melatonin (Nutricentury: 3 or 6 mg) taking 1 hour before bed time

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinic

Full name of responsible person

Dr. Mohammad Reza Mohammadi

Street address

Dr. Mohammad Reza Mohammadi private clinic, Zafar street, Vali-Asr street, Tehran. Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zahra Ahadi

Street address

Research Deputy of Tehran University of Medical Sciences, Keshavarz Avenue, Tehran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyed Ali Mostafavi

Position

B.S.

Other areas of specialty/work

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Email

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty