

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5541 3540

###### Email address

pprc@sina.tums.ac.ir

##### 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 befor 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**

Rasearch 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**

**Street address**

4th floor, Nutrition department, Health faculty, Tehran University of Medical Sciences

**City**

Tehran

**Postal code**

**Phone**

00

**Fax**

**Email**

mostafavi.n80@hotmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyed Ali Mostafavi

**Position**

BS

**Other areas of specialty/work**

**Street address**

4th floor, Nutrition department, Health faculty, Tehran University of Medical Sciences

**City**

Tehran

**Postal code**

**Phone**

00

**Fax**

**Email**

mostafavi.n80@hotmail.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyed Ali Mostafavi

**Position**

BS

**Other areas of specialty/work**

**Street address**

4th floor, Nutrition department, Health faculty, Tehran University of Medical Sciences

**City**

Tehran

**Postal code**

**Phone**

00

**Fax**

**Email**

mostafavi.n80@hotmail.com

**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*