

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of sleep disorders in adult Attention deficit hyperactivity disorder patients treated with immediate-release methylphenidate and modified-release methylphenidate

#### Protocol summary

##### Study aim

Comparison of sleep quality of ADHD patient after continuous release of methylphenidate with rapid release of methylphenidate

##### Design

Randomized clinical trial, self-control of each individual, with cross-over design, non-blind, on 30 patients, randomization with toolbox software, and followed for 2 month

##### Settings and conduct

People over the age of 18 who have been diagnosed with ADHD based on a DSM-V by psychiatric clinical interview at Roozbeh Psychiatric Hospital and also confirmed a ADHD diagnosis by a semi-structured DIVA clinical interview conducted by a trained psychologist. Have been nominated for methylphenidate,

##### Participants/Inclusion and exclusion criteria

adult Patients diagnosis attention deficit hyperactivity disorder start treatment with methylphenidate Exclusion criteria: Taking any stimulant in the past month Drug abuse Taking sleeping pills Major psychiatric disorders Severe hypertension, heart failure, arrhythmia, hyperthyroidism and thyrotoxicosis, myocardial infarction and angina, glaucoma History of tics and Toure syndrome Existence of neurological diseases that accompany sleep disorders Serious side effects of methylphenidate Patient dissatisfaction with entering or continuing the study

##### Intervention groups

Intervention group 1: Intervention group 1: For 4 weeks, they will be treated with methylphenidate with rapid release made by Pursina company and then for 1 week without drug and then treated with continuous release drug form made by Sandoz company. Intervention group 2: They will be treated for 4 weeks with continuous release methylphenidate made by Sandoz company and then for 1 week without medicine and then treated with

a quick release drug form made by Pursina company.

##### Main outcome variables

Anxiety, daily activity, duration and quality of sleep at the beginning and end of each period with the Pittsburgh Questionnaire ; Epworth Sleepiness Scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201101049214N1**

Registration date: **2021-01-27, 1399/11/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-01-27, 1399/11/08**

Update count: **0**

##### Registration date

2021-01-27, 1399/11/08

##### Registrant information

##### Name

masoud esfahani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3332 8065

##### Email address

masoudsfhn@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-21, 1399/09/01

##### Expected recruitment end date

2021-11-22, 1400/09/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of sleep disorders in adult Attention deficit hyperactivity disorder patients treated with immediate-release methylphenidate and modified-release methylphenidate

**Public title**

effect of modified-release methylphenidate in sleep

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

adult Patients diagnosis attention deficit hyperactivity disorder start treatment with methylphenidate

**Exclusion criteria:**

History of taking any stimulant in the past month Drug abuse Taking sleeping pills such as benzodiazepines or zolpidem Major psychiatric disorders such as bipolar disorder, psychotic disorders, autism and major depression Severe hypertension, heart failure, arrhythmia, hyperthyroidism and thyrotoxicosis, myocardial infarction and angina, glaucoma History of tics and Toure syndrome Existence of neurological diseases that accompany sleep disorders such as epilepsy, vascular disorders, history of stroke, movement and Parkinson's disorders, dementia and cognitive disorders Serious side effects of methylphenidate such as seizures Patient dissatisfaction with entering or continuing the study

**Age**

From **18 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

e Pittsburgh Sleep Quality Index (PSQI) , Epworth Sleepiness Scale

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random Generator using results from random number generation software such as "Toolbox" application

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The Institute of Pharmaceutical Sciences -Tehran University of Medical Sciences

**Street address**

No. 41, Farz Mahdi Alley, Modares Ave

**City**

qazvin

**Province**

Qazvin

**Postal code**

3413859478

**Approval date**

2021-01-24, 1399/11/05

**Ethics committee reference number**

IR.TUMS.TIPS.REC.1399.155

**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

**2****Description of health condition studied**

sleep disorders

**ICD-10 code**

F51

**ICD-10 code description**

Sleep disorders not due to a substance or known physiological condition

**Primary outcomes****1****Description**

. Anxiety, daily activity, duration and quality of sleep at the beginning and end of each period with the Pittsburgh Questionnaire

**Timepoint**

At the beginning of the study and at 4 and 8 weeks of treatment

**Method of measurement**

Face-to-face interview with the patient

## 2

### Description

Epworth Sleepiness Scale

### Timepoint

At the beginning of the study and at 4 and 8 weeks of treatment

### Method of measurement

Face-to-face interview with the patient

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Intervention group 1: For 4 weeks, they will be treated with methylphenidate with rapid release made by Pursina company and then for 1 week without drug and then treated with continuous release drug form made by Sandoz company.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: They will be treated for 4 weeks with continuous release methylphenidate made by Sandoz company and then for 1 week without medicine and then treated with a quick release drug form made by Pursina company.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Roozbeh Psychiatry Hospital

##### Full name of responsible person

Masoud Esfahani

##### Street address

No. 41, Farz Mahdi Alley, Modares Ave

##### City

qazvin

##### Province

Qazvin

##### Postal code

3413859478

##### Phone

+98 28 3332 8056

##### Fax

##### Email

masoudsfhn@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

MOHAMMAD ALI SAHRAIAN

##### Street address

Vice Chancellor for Research and Technology, sixth floor, Central University Organization, corner of Quds Street, ,Keshavarz Boulevard,

##### City

tehran

##### Province

Tehran

##### Postal code

1417653761

##### Phone

+98 21 8163 3619

##### Fax

+98 21 8163 3623

##### Email

rmo@tums.ac.ir

##### Web page address

<https://rmo.tums.ac.ir/main>

#### 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

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

Tehran University of Medical Sciences

##### Full name of responsible person

Masoud Esfahani

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

No. 41, farz mahdi, modares Ave, qazvin

##### City

Qazvin  
**Province**  
Qazvin  
**Postal code**  
3413859478  
**Phone**  
+98 28 3332 8065  
**Fax**  
**Email**  
masoudsfhn@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Masoud Esfahani  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
No. 41, farz mahdi, modares Ave, qazvin  
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**Fax**  
**Email**  
masoudsfhn@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Masoud Esfahani  
**Position**  
Resident  
**Latest degree**  
Medical doctor

**Other areas of specialty/work**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Changes in people's sleep scores Change sleeping and waking habits

### When the data will become available and for how long

After publishing the article

### To whom data/document is available

Researchers in scientific and academic centers

### Under which criteria data/document could be used

At the request of reputable person for scientific development of the topic Coded and raw data

### From where data/document is obtainable

masoudesfahani007@yahoo.com

### What processes are involved for a request to access data/document

Request in the form of a mail with the sender's details and also the reason for the need for the required data if agree, as soon as possible

### Comments