

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
City
Qazvin
Province
Qazvin
Postal code
3413859478
Phone
+98 28 3332 8065
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
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

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