

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effect of Agomelatine on polysomnography parameters in patients with obstructive sleep apnea

Protocol summary

Study aim

Determination of agomelatine effects on polysomnography parameters

Design

This study is a randomized, parallel-group and double-blind. Seventy patients with obstructive sleep apnea are randomly divided into intervention or control groups.

Settings and conduct

Place of study: Dr Masih Daneshvari Hospital
How to do the study: Seventy patients with obstructive sleep apnea are divided randomly into intervention or control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with age above 18 years old with obstructive sleep apnea that refer to the Sleep Clinic of Masih Daneshvari Hospital. Exclusion criteria: Pregnancy, breastfeeding, neurological disease, use of stimulant drugs, allergy to agomelatine or formulation components, having stage 2 or 3 of liver failure, ciprofloxacin consumption, fluvoxamine consumption

Intervention groups

Patients in the intervention group receive 50mg agomelatine (Tadbir Kalay-e Jam Pharmaceutical company, Iran) one hour before sleep, for three nights and patients in the control group do not receive agomelatine.

Main outcome variables

Evaluating effects of agomelatine on sleep onset, sleep duration, sleep efficiency and sleep stages.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N26**

Registration date: **2021-06-13, 1400/03/23**

Registration timing: **prospective**

Last update: **2021-06-13, 1400/03/23**

Update count: **0**

Registration date

2021-06-13, 1400/03/23

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

f_dastan@sbm.u.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-02, 1400/04/11

Expected recruitment end date

2022-01-01, 1400/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Agomelatine on polysomnography parameters in patients with obstructive sleep apnea

Public title

Evaluating the effect of Agomelatine in patients with obstructive sleep apnea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with age above 18 years old with obstructive sleep apnea that refer to the Sleep Clinic of Masih Daneshvari Hospital.

Exclusion criteria:

Pregnancy Breastfeeding Neurological disease (stroke, epilepsy, tumor, previously neurological manipulation) Use of stimulant drugs Allergy to Agomelatine or formulation components Having stage 2 or 3 of liver failure Ciprofloxacin consumption Fluvoxamine consumption

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method and random number table was used in this study.

Blinding (investigator's opinion)

Double blinded

Blinding description

Care provider and outcome assessor and data analyst are blind to the study groups until the end of the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Pharmacy and Nursing and Midwifery Shahid Beheshti University of Medi

Street address

3rd floor, School of Medicine, Evin St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2020-02-03, 1398/11/14

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.280

Health conditions studied

1

Description of health condition studied

Obstructive sleep apnea

ICD-10 code

G47.33

ICD-10 code description

Obstructive sleep apnea (adult) (pediatric)

Primary outcomes

1

Description

The assessment of polysomnography parameters

Timepoint

The assessment of polysomnography parameters 2 days after agomelatine consumption

Method of measurement

With measurement of recorded criteria in the polysomnography test response

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group, receive two 25 mg agomelatine tablets of Tadbir Kalay-e Jam pharmaceutical company one hour before bedtime, two nights before sleep test and the night of sleep test.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group do not receive Agomelatine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Farzaneh Dastan

Street address

Masih Daneshvari Hospital, Shahid Bahonar street
(Niyavaran), Darabad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hassan Yazdan Panah

Street address

Shahid Beheshti Faculty of Pharmacy, Niayesh
Highway, Valiasr Ave, Tehran, Iran

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yazdanpanah@sbmu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Behnaz Gholizade Niari

Position

pharmacy student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Position

Pharmacy student

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

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

Title and more details about the data/document

All the potential data can be shared after blinding.

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

Six months after publishing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes

From where data/document is obtainable

Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital,
Daar-Abad, Niavaran

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

Official letter to the researchers through Email
(fzh.dastan@gmail.com).

Comments