

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Sep 2026

The effect of melatonin on sleep quality, mental health and performance in patients with drug abuse in methadone-treated patients

Protocol summary

Study aim

The effect of melatonin on sleep quality, mental health and performance in patients with drug abuse in methadone-treated patients

Design

The study of clinical trial with control group, with parallel, double-blind, randomized, phase 3 on 105 patients, will be done by randomization method (random allocation software)

Settings and conduct

Before the intervention, all three groups will complete the questionnaires. Then, participants will be divided into three groups (melatonin, zolpidem, placebo) using random allocation software. Subjects in the Zolpidem group will take a 10 mg tablet just before bedtime by the patient. People in melatonin group will use three 3 mg tablets half an hour before bedtime. In the placebo group, subjects will receive starch-filled capsules. Blinding is done for the patient and the analyzer. The forms will be completed by the participants before and 4 weeks after the intervention. This study will be conducted in outpatient drug abuse treatment centers in Isfahan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years of age with drug abuse who have been taking methadone for at least three months and have a PSQI score above 5. Exclusion criteria: Severe sensitivity to zolpidem or melatonin; pregnancy; lactation.

Intervention groups

Subjects in zolpidem group will take a 10 mg tablet just before bedtime by the patient. People in melatonin group will use three 3 mg tablets half an hour before bedtime. In the placebo group, subjects will take starch-filled capsules.

Main outcome variables

Sleep quality; mental health; sexual function; general health.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201214049718N1**

Registration date: **2021-01-25, 1399/11/06**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-25, 1399/11/06**

Update count: **0**

Registration date

2021-01-25, 1399/11/06

Registrant information

Name

Negin Etminani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3274 7970

Email address

n.etminani1394@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-04-20, 1400/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin on sleep quality, mental health and performance in patients with drug abuse in methadone-treated patients

Public title
The effect of melatonin on sleep quality, mental health and performance in patients with drug abuse in methadone-treated patients

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in research Over 18 years of age Having writing literacy Substance abuse confirmed by positive urine tests PSQI score above 5 No neurological, neuro-psychotic or autoimmune disease, cancer, lung disease, class 4 heart failure or unstable angina No taking benzodiazepines, anticonvulsants, aspirin, beta-blockers, calcium channel blockers, NSAIDs, dexamethasone, lithium, melatonin, and antidepressants such as serotonin reuptake inhibitors. Not working in night shift Taking methadone for at least 3 months
Exclusion criteria:
If there is a crisis or un foreseeable disaster during the research. Changes in treatment protocol for any reason before the intervention Severe allergic reaction to melatonin and zolpidem Pregnancy or Lactation

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization process is a simple randomization method using Random allocation software . We list the people who have the inclusion criteria and consent to participate in the study according to the three digits to the right of the national code from 1 to 105 and then using Random allocation software is divided into three groups a: Melatonin, group b: Zolpidem, group c: control. In front of each number, the assigned group is created.

Blinding (investigator's opinion)
Double blinded

Blinding description
Responsible for collecting questionnaire information and analyzing statistics will be unaware of the placement of people in groups. Coding of people is done based on the first name and surname and father's name and the last three digits of the national code. Does not know about the assignment of individuals in groups, will give the questionnaires to the participants before and one month after the start of the study and enters the data into SPSS and this data will be analyzed by the analyzer if it is not

in the coding process.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Building 56, No. 6, Khaju St
City
Isfahan
Province
Isfahan
Postal code
8153743361

Approval date
2020-12-12, 1399/09/22

Ethics committee reference number
IR.MUI.MED.REC.1399.813

Health conditions studied

1

Description of health condition studied
Patients with drug abuse, people treated with methadone

ICD-10 code
Z71.5

ICD-10 code description
Drug abuse counseling and surveillance

Primary outcomes

1

Description
Sleep Quality Score in Petzburg Sleep Quality Questionnaire

Timepoint
Before and 4 weeks after intervention

Method of measurement
Petzburg Sleep Quality Questionnaire

2

Description
Mental health score in Depression, Anxiety, Stress Scale-21

Timepoint
Before and 4 weeks after intervention

Method of measurement

Depression, Anxiety, Stress Scale-21

3

Description

Sexual function score in International Index of Erectile Function Questionnaire

Timepoint

Before and 4 weeks after intervention

Method of measurement

International Index of Erectile Function Questionnaire

4

Description

General health score in General Health Questionnaire-28

Timepoint

Measurement of general health score before the intervention and 4 weeks after the taking of melatonin or zolpidem or placebo

Method of measurement

General Health Questionnaire-28

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, patients will use three 3 mg melatonin tablets made by Razak company half an hour before bedtime for 4 weeks. In addition to melatonin, these patients receive methadone syrup made by Darou Pakhsh Company in the morning and evening (4 hours before bedtime) according to the required dose for 4 weeks.

Category

Rehabilitation

2

Description

Intervention group 2: In this group, patients will take a 10 mg zolpidem tablet made by Sobhan Company for 4 weeks before bedtime. In addition to zolpidem, these patients receive methadone syrup made by Darou Pakhsh Company in the morning and evening (4 hours before bedtime) according to the required dose for 4 weeks.

Category

Rehabilitation

3

Description

Control group: In this group, patients will take a capsule filled with starch as placebo for 4 weeks at night before bedtime. In addition to placebo, these patients will receive methadone syrup made by Darou Pakhsh

Company in the morning and evening (4 hours before bedtime) according to the required dose for 4 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient Drug Abuse Treatment Centers in Isfahan

Full name of responsible person

Zahra Amini

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Faculty of Medicine, Isfahan University of Medical Sciences, Hezar Jerib St.

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8174673461

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zahraamini63@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research, Isfahan University of Medical Sciences

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Zahra Amini
Position
Associate professor
Latest degree
Specialist
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

Total potential data is shareable after unre identifying people

When the data will become available and for how long

Starting access period 6 months after printing results

To whom data/document is available

It will be available for researchers working in academic and scientific institutions, as well as those working in the industry

Under which criteria data/document could be used

Use in other articles

From where data/document is obtainable

zahraamini63@gmail.com

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

After reading the e-mail and preparing the request

answer, the answer will be given as soon as possible
Comments