Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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 Sever 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
Isfehan

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 Internation Index of Erectile Function Questionnaire
Timepoint
Before and 4 weeks after intervention
Method of measurement
Internation 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
Street address
Faculty of Medicine, Isfahan University of Medical Sciences, Hezar Jerib St.
City
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8174673461
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Email
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
Street address
Building 56, No. 6, Khaju St
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n.etminani1394@gmail.com
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

Public Health/Community Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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