

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Melatonin Supplementation on Mental Health, Stem Cells Mobilization and central nervous system function among Methamphetamine Users: Behavioral, Biochemical

Protocol summary

Study aim

Evaluation of The Effect of Melatonin Supplementation on Mental Health, Stem Cells Mobilization and central nervous system function among Methamphetamine Users: Behavioral, Biochemical Evaluation

Design

The clinical trial has an intervention group and a control group. Samples are divided into groups using block randomization method.

Settings and conduct

This investigation designed to determine the effect of melatonin supplementation on mental health parameters, metabolic and genetic profiles in patients with Methamphetamine Abuse Disorder. In this Study, Participants are randomly allocated divide into two groups (intervention and control). for the intervention group, Participants receive either 10 mg melatonin (2 melatonin capsules, 5 mg each)once a day 1 hour before bedtime for 4 weeks. In this study, evaluators and analyzers are blinded to groups.

Participants/Inclusion and exclusion criteria

Male: be aged between 18 and 55: methamphetamine dependence: have a methamphetamine use history longer than 12 months; No an intellectual disability: No psychiatric illness: No current medical illness

Intervention groups

In This Study for the intervention group, Participants receive either 10 mg melatonin (2 melatonin capsules, 5 mg each)once a day 1 hour before bedtime for 4 weeks. The subjects in the control group were evaluated without receiving melatonin during the same period.

Main outcome variables

Assessing the amount of Mobilization of Hematopoietic Stem Cells in the Plasma; Quality of Sleep; Depression Rate; Anxiety Rate; Evaluation of Brain-Derived Neurotrophic Factor

General information

Reason for update

Examining some factors that can be helpful in examining the possible outcome of the study and possible results.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200521047533N1**

Registration date: **2021-05-24, 1400/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-31, 1401/05/09**

Update count: **1**

Registration date

2021-05-24, 1400/03/03

Registrant information

Name

Ali reza Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Melatonin Supplementation on Mental Health, Stem Cells Mobilization and central nervous system function among Methamphetamine Users: Behavioral, Biochemical

Public title

The effect of melatonin on the side effects of methamphetamine

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

have a methamphetamine use history longer than 12 months; Male No history of severe Neurological disease No history of severe Head Trauma Do not take psychiatric drugs now

Exclusion criteria:

Having severe psychological illness Having blood diseases

Age

From **18 years** old to **55 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Permuted block randomization is used. I. Randomization type, details of any restrictions (such as blocking and block size) Because patients gradually enter the study and the 4-volume block method is used to make the sample size the same in the two groups. For this purpose, 6 quadruple blocks will be created as follows 1-AABB 2- ABAB 3-ABBA 4-BBAA 5-BABA 6-BAAB Where A is for the intervention group and B is for the control group. The random assignment will be done in such a way that first a random number will be created in Excel from 0 to 9. Depending on which block the random number belongs to, the sequence of that block will be used to assign patients to the control and intervention groups. For example, if the random number generated is 6, the first person will be assigned to group B, the second person to group A, the third person to group A, and the fourth person to group B. To reach the calculated sample size, the random number creation will be repeated 12 times. Because each time the repetition task is assigned, four patients are identified (56 random sequences, each group of 28 people will be produced taking into account the drop). It should be noted that if the random number generated is 7, 8, 9 and 0, it will be ignored. II. Participant allocation concealment method (mechanism used to randomize participant allocation (such as consecutive numbered containers) and explain

all the steps that can be taken to hide the sequence until the intervention is assigned to each group) Envelopes in which the specified group is placed are used to conceal the allocation. Envelopes are numbered. After filling in the basic information of the people, an envelope is opened according to the order of entry of the people and the person is assigned to the desired group. That is, 56 envelopes of one shape will be prepared based on the order of A and B above and will be numbered from 1 to 56, respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

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

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shahroud

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Approval date

2021-02-07, 1399/11/19

Ethics committee reference number

IR.SHMU.REC.1399.173

Health conditions studied**1****Description of health condition studied**

Methamphetamine Addiction

ICD-10 code

F15.1

ICD-10 code description

Other stimulant abuse

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

Evaluation of percentage of circulating stem cells in the blood by measuring CD + 34 and CD45 markers

Timepoint

Pre and Post Treatment
Method of measurement
Flow cytometry

Secondary outcomes

1

Description

Sleep Quality

Timepoint

Pre and Post Treatment (beginning of the study and after 28 days of melatonin treatment)

Method of measurement

Pittsburgh Sleep Quality Index

2

Description

Evaluation of patients' depression

Timepoint

Pre and Post Treatment (beginning of the study and after 28 days of melatonin treatment)

Method of measurement

Beck Depression Inventory

3

Description

Evaluation of patients' anxiety

Timepoint

Pre and Post Treatment (beginning of the study and after 28 days of melatonin treatment)

Method of measurement

Beck Anxiety Inventory

4

Description

Brain-derived neurotrophic factor (BDNF)

Timepoint

Pre and Post Treatment (beginning of the study and after 28 days of melatonin treatment)

Method of measurement

Enzyme-linked Immunosorbent Assay (ELISA) kits

5

Description

Glial fibrillary acidic protein (GFAP)

Timepoint

Pre and Post Treatment (beginning of the study and after 28 days of melatonin treatment)

Method of measurement

Enzyme-linked Immunosorbent Assay (ELISA) kits

6

Description

measures brain activity by Functional magnetic resonance imaging(fMRI)

Timepoint

Pre and Post Treatment (beginning of the study and after

28 days of melatonin treatment)

Method of measurement

Using Functional magnetic resonance imaging(fMRI)

7

Description

Anatomical study of white matter fibers

Timepoint

Pre and Post Treatment (beginning of the study and after 28 days of melatonin treatment)

Method of measurement

Using Diffusion tensor imaging (DTI)

8

Description

Investigating changes in Cognitive and functional brain factors such as memory and executive function using the Cambridge Neuropsychological Test Automated Battery (CANTAB)

Timepoint

Pre and Post Treatment (beginning of the study and after 28 days of melatonin treatment)

Method of measurement

Using the Cambridge Neuropsychological Test Automated Battery(CANTAB)

Intervention groups

1

Description

Intervention group: Participants receive either 10 mg melatonin (2 melatonin capsules, 5 mg each)once a day 1 hour before bedtime for 4 weeks.

Category

Treatment - Drugs

2

Description

Control group: Participants in this group did not receive any medication for 4 weeks due to this study.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

center Of Recovery and Rehabilitation For Substance Abuse Disorders(Towards a better tomorrow)

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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
Shahroud 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

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Fax**Email**

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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

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

Not applicable

Title and more details about the data/document

Because this project is my graduate dissertation, the results can be published in the dissertation as well as scientific articles and made available to the public.

When the data will become available and for how long

6 months after the publication of dissertations and articles

To whom data/document is available

Scientific research centers and addiction therapists

Under which criteria data/document could be used

Use of data along with mentioning the name of the data collection source and the main researchers

From where data/document is obtainable

By email and communication with the scientific director of the project

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

After receiving the applicant's email and reviewing it within a maximum of 2 months

Comments