

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A Clinical trial to assess the effect of melatonin supplementation compared with the placebo on mental health parameters, metabolic profiles and genetic response in methadone maintenance treatment patients

Protocol summary

Study aim

The aim of this study is to determine the effects of melatonin supplementation on mental health parameters, metabolic profiles and genetic response in methadone maintenance treatment patients.

Design

Study design: Parallel double-blind (both patients and researchers) randomized controlled clinical trial.

Settings and conduct

Population and sample size: 60 eligible patients on methadone maintenance treatment referred to Gholabchi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients on methadone maintenance treatment and aged 25 to 70 years will be included in this study. Exclusion criteria: Unwillingness to cooperate.

Intervention groups

Intervention: Patients will be assigned to receive either melatonin (n=30) or placebo (n=30).

Main outcome variables

Total antioxidant (primary outcome), other metabolic profiles, mental health parameters and genetic response (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072933551N3**

Registration date: **2017-08-17, 1396/05/26**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-15, 1398/06/24**

Update count: **2**

Registration date

2017-08-17, 1396/05/26

Registrant information

Name

Amir Ghaderi

Name of organization / entity

Kashan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-08-03, 1396/05/12

Expected recruitment end date

2017-08-21, 1396/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial to assess the effect of melatonin supplementation compared with the placebo on mental health parameters, metabolic profiles and genetic response in methadone maintenance treatment patients

Public title

Effect of melatonin supplementation in treatment of maintenance methadone treatment patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients on maintenance methadone treatment Age of 25 to 70 years

Exclusion criteria:

Taking melatonin, multivitamin-mineral and antioxidant supplements during the last 3 months before the intervention Taking anti-inflammatory agents History of metabolic diseases including diabetes, hypertension, thyroid and cardiovascular disease

Age

From **25 years** old to **70 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo has been used to achieve masking of participants and investigators. The researchers and patients will be concealed until the final analyses by a trained staff.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

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Isfahan

Postal code

8814187159

Approval date

2017-08-02, 1396/05/11

Ethics committee reference number

IR.Kaums.REC.1396.50

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

Addiction

ICD-10 code

F19

ICD-10 code description

Mental and behavioural disorders due to multiple drug use and use of other psychoactive substances

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

Total antioxidant

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

Secondary outcomes**1****Description**

HDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2**Description**

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

3**Description**

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4**Description**

Fasting plasma glucose

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

5**Description**

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

6**Description**

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

7**Description**

Hs-CRP

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

8**Description**

Depression beck score

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

9**Description**

Anxiety beck score

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

10**Description**

Expressed levels of LL-1 gene

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

PCR

11**Description**

Expressed levels of LL-8 gene

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

PCR

12**Description**

Expressed levels of TNF-a gene

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

PCR

13**Description**

Expressed levels of PPAR-γ

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

PCR

14**Description**

Total glutathione

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

Spectrophotometry

15**Description**

Malondialdehyde

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Melatonin supplements (NUTRALab, Scarborough, Canada), 5 mg, two oral capsules, one hour before bedtime for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo oral capsule (Barij Essence, Kashan, Iran), two capsules one hour before bedtime for 12 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gholabchi Clinic

Full name of responsible person

Zatollah Asemi

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Shahid Rajaei Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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

Vice chancellor for research, Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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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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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No - There is not a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available