Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of the effect of melatonin supplementation compared with the placebo on clinical status, metabolic profiles and gene expression related to inflammation, insulin and lipid in patients with Parkinson's disease

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of melatonin supplementation on clinical status, metabolic profiles and gene expression related to inflammation, insulin and lipid in patients with Parkinson's disease.

Design

Study design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive melatonin supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with Parkinson's disease referred to Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Parkinson' disease; aged 50 to 90 years. Exclusion criteria: Unwillingness to cooperate.

Intervention groups

Intervention group: Melatonin supplements (Zahravi, Tabriz, Iran), 5 mg, two capsules one hour before bedtime for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), two capsules one hour before bedtime for 12 weeks orally.

Main outcome variables

Outcomes: Hs-CRP (primary outcome) and UPDRS, biomarkers of oxidative stress, lipid profile, markers of insulin metabolism and gene expression related to insulin, lipid and inflammation (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

The revisions were accordance with the original approved proposal.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N29**
Registration date: **2018-01-23, 1396/11/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-14, 1399/02/25**
Update count: **2**

Registration date

2018-01-23, 1396/11/03

Registrant information

Name
Mohammadreza Sharif

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 5546 3378

Email address
ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-02, 1396/10/12

Expected recruitment end date
2018-02-01, 1396/11/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of the effect of melatonin supplementation compared with the placebo on clinical status, metabolic profiles and gene expression related to inflammation, insulin and lipid in patients with Parkinson's disease

Public title
Effect of melatonin supplementation in treatment of patients with Parkinson's disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Patients with Parkinson' disease. Individuals aged 50 to 90 years.
Exclusion criteria:
Exclusion criteria: Unwillingness to cooperate
Age
From **50 years** old to **90 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to receive supplement or placebo. Randomization will be done by the use of computer-generated random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.
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
City
Kashan
Province
Isfehan
Postal code
8115187159
Approval date
2018-01-01, 1396/10/11
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1396.93

Health conditions studied

1

Description of health condition studied
Parkinson's disease
ICD-10 code
G20
ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
ELISA test

Secondary outcomes

1

Description
UPDRS
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Physical Examination by Neurologist

2

Description
Malondialdehyde
Timepoint

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

Method of measurement

Spectrophotometry

3

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

4

Description

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

5

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

6

Description

Insulin

Timepoint

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

Method of measurement

Elisa kit

7

Description

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

8

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

9

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

10

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

11

Description

Expressed levels of TNF-a gene

Timepoint

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

Method of measurement

PCR

12

Description

Expressed levels of IL-8 gene

Timepoint

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

Method of measurement

PCR

13

Description

Expressed levels of TGF-β gene

Timepoint

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

Method of measurement

PCR

14

Description

Expressed levels of PPAR-γ gene

Timepoint

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

Method of measurement

PCR

15

Description
Expressed levels of LDL-R gene
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
PCR

16

Description
PSQI
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questioner

17

Description
BAI
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questioner

18

Description
BDI
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Questioner

Intervention groups

1

Description
Intervention group: Melatonin supplements (Zahravi, Tabriz, Iran), 5 mg, two capsules one hour before bedtime for 12 weeks orally.
Category
Treatment - Drugs

2

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

Recruitment centers

1

Recruitment center
Name of recruitment center
Naghavi Clinic
Full name of responsible person
Zatollah Asemi
Street address
Shahid Rajaee Avenue, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 4446 0180
Email
asemi_z@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ghotbe Ravandi Boulevard, Kashan
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+98 31 4446 0180
Email
asemi_z@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Nutritionist
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Other areas of specialty/work
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Person responsible for updating data

Contact

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Other areas of specialty/work
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8115187159
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Fax
Email
asemi_z@kaums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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