Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A triple blinded randomized controlled trial of oral Melatonin in elevated blood pressure individuals

Protocol summary

Study aim

To evaluate the effects of melatonin or placebo on systolic and diastolic blood pressure , hs- CRP, IL-6, TNF-alpha and ICAM-1level, lipid profile , fasting blood sugar and sleeping pattern

Design

A two arms parallel group concealed randomized trial with triple blinding , phase three with 320 participants

Settings and conduct

Elevated blood pressure individuals will be assigned to intervention group of standardized diet for lowering blood pressure , exercise and 3 Mg Melatonin capsule versus control group receiving standardized diet for lowering blood pressure , exercise and placebo. Patients , medical providers and outcome evaluators are all blinded.Data analyzer and project evaluation committee will also be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals with systolic blood pressure120-129 or diastolic blood pressure =80mmHg, New cases, Age range of 30-60, Negative pregnancy test for women, Baseline melatonin and biomarkers level, liver function tests within normal range; Exclusion criteria: Previous history of hypersensitivity of melatonin, Past history of using antihypertensive treatment, hypertension, cardiovascular diseases, diabetes mellitus, and epilepsy, Use of beta-blockers, sleep aids, warfarin, flaxseed, soy and supplements

Intervention groups

Intervention group: Three weeks melatonin 3 Mg capsule one hour before bedtime along with a careful plan of heart-healthy diet, aerobic exercise of 5 times a week each time 30 minutes. Control group: Heart-healthy diet, aerobic exercise of 5 times a week each time 30 minutes and placebo capsule one time one hour before bedtime for three weeks.

Main outcome variables

Primary out comes: Change in systolic and diastolic blood pressure Change in lipid profile and inflammatory markers secondary outcomes: Change in sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181003041218N2**
Registration date: **2019-01-05, 1397/10/15**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-05, 1397/10/15**
Update count: **0**

Registration date

2019-01-05, 1397/10/15

Registrant information

Name

zinat hatmi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6405 3219

Email address

hatmizn@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A triple blinded randomized controlled trial of oral Melatonin in elevated blood pressure individuals

Public title
Melatonin in elevated blood pressure

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Systolic blood pressure 120-129 Diastolic blood pressure =80 mm Hg Age range of 30-60 years Negative pregnancy test for women at productive age Baseline Melatonin and biomarkers level and complete liver function tests within normal range

Exclusion criteria:
Past history of using antihypertensive treatment Past medical history of hypertension, cardiovascular diseases, (i.e. coronary artery disease), and diabetes mellitus, epilepsy Use of beta-blockers, sleep aids, warfarin, flaxseed and soy supplements Previous history of hypersensitivity of melatonin

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **320**

Randomization (investigator's opinion)
Randomized

Randomization description
Balanced randomization by using random blocks. Unit of randomization: Individual patients Randomization tool: Sealed envelope containing intervention group By using random block tables, 80 blocks of 4 members according to a total of 320 sample size will be chosen. Within each block there will be 2 interventions and 2 placebos. Permutations will be random and allocation to the study groups will be applied by using sealed envelope. Allocation concealment: Randomization will be assigned at the central office of design and performance of the trial. Patients and medical providers will be unaware of the randomization scheme and study groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Triple blinding is planned. All participants, health care, data collectors and outcome assessors will be blinded about treatment arms. Data analyzer and person who is responsible for project monitoring will also be blinded. Blinding and assignment of interventional groups will be performed at central office of the trial and health care providers and outcome evaluators will be all blinded about the process. A Concealment envelope will assign patients to intervention group according to random block table. Melatonin and placebo capsule will be identical for keeping patients and medical providers blinded.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Second floor, Building Number 1, Purcina Ave., Keshavarz Bulevard, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417613151

Approval date
2018-09-17, 1397/06/26

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.438

Health conditions studied

1

Description of health condition studied
Elevated blood pressure

ICD-10 code
I15

ICD-10 code description
Secondary hypertension

Primary outcomes

1

Description
Mean of systolic blood pressure change in mm Hg from baseline

Timepoint
Before intervention and 3 weeks later

Method of measurement
In clinic with standardized sphygmomanometer

2

Description
Mean of diastolic blood pressure change in mm Hg from baseline
Timepoint
Before intervention and 3 weeks later
Method of measurement
In clinic with standardized sphygmomanometer

3

Description
Mean cholesterol change in mg/dl from baseline
Timepoint
Before intervention and 3 weeks later
Method of measurement
Enzymatic laboratory method

4

Description
Mean low density lipoprotein change in mg/dl from baseline
Timepoint
Before intervention and 3 weeks later
Method of measurement
Enzymatic laboratory method

5

Description
Mean high sensitive CRP change in mg/l from baseline
Timepoint
Before intervention and 3 weeks later
Method of measurement
Laboratory method

Secondary outcomes

1

Description
Ċhange in sleep quality score
Timepoint
Before intervention and 3 weeks later
Method of measurement
Pittsburg Sleep Quality inventory

Intervention groups

1

Description
Intervention group:Melatonin 3 mg oral capsule once one hour before bedtime for three weeks along with lifestyle intervention according to 2013 American heart association guideline. Melatonin capsules will made in Iran.
Category
Prevention

2

Description
Control group: oral placebo capsule once one hour before bedtime for three weeks along with lifestyle interventionaccording to 2013 American heart association guideline. Placebo capsules will made in Iran.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Out patient clinic medical faculties of Tehran University of Medical Sciences
Full name of responsible person
Zinat Hatmi
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Second floor, Building Number 1, Purcina Ave, Keshavarz Bulevard, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Ali Sahraiian
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Grant name

A triple blinded randomized controlled trial of oral Melatonin in elevated blood pressure individuals

Grant code / Reference number
38890

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

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Dr Zinat Hatmi

Position
professor at TUMS

Latest degree
Specialist

Other areas of specialty/work
Cardioprevention

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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
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

No - There is not a plan to make this available

Title and more details about the data/document

Just risk factors data without patients name

When the data will become available and for how long

After completing the final report and publication of the manuscript

To whom data/document is available

Authors who decides to write a systematic review

Under which criteria data/document could be used

Copy rights

From where data/document is obtainable

Published article

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

Delivering a research proposal

Comments

Data will be published in the upcoming article