Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Melatonin administered postoperatively lowers oxidative stress and inflammation and significantly recovers heart function in patients undergoing CABG Surgery

Protocol summary

Study aim

Evaluation of effects of melatonin on heart function and inflammatory and oxidant biomarkers in patients after CABGS.

Design

Clinical trial with a control group, with parallel groups, double-blind, phase 3 on 60 patients. R software version 3.6.3 was used for randomization

Settings and conduct

Patients undergoing CABG surgery at Bushehr Heart Center after discharge from the hospital will complete the consent form and questionnaire. Then 10cc blood sample will be collected from them after consuming melatonin and a placebo for a period of 60 days period of intervention. The project manager, the only person who knows about the codes and the order of assigning people to groups, is not involved in any of the stages of evaluating and measuring the results. On the other hand, the shape, size, and type of packaging of drugs and placebo are completely the same, so the patient and the outcome assessor will not know the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Intention of the patients to participate in the trial, Having no addiction to any drugs or alcohol. Not having mental or psychological disorders. Absence of chronic diseases such as kidney, liver, digestive, and bone diseases. Exclusion criteria: Occurrence of any problems related to surgery, such as heart attack, cardiac arrhythmia, bleeding at the surgical site, myocardial damage, etc.,

Intervention groups

The case group will be given melatonin (5 mg and 10 mg capsules, once a night for 60 days). The control group will be without melatonin

Main outcome variables

Heart Function, including: Ejection Fraction, Atrial fibrillation(AF), ECG, blood pressure(diastolic and Systolic).CK-MB enzyme, LDH enzyme, troponin T, total antioxidant capacity (TAC), malondialdehyde (MDA), TNF-a, hs - CRP, nitric oxide synthase (NO)

General information

Reason for update

Title updated to be more appropriate Randomization method has been modified

Acronym

IRCT registration information

IRCT registration number: **IRCT20111119008129N14**
Registration date: **2023-08-01, 1402/05/10**
Registration timing: **prospective**

Last update: **2025-02-18, 1403/11/30**
Update count: **1**

Registration date

2023-08-01, 1402/05/10

Registrant information

Name

Ali Movahed

Name of organization / entity

Country

Iran (Islamic Republic of)

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a.movahed@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-02-12, 1402/11/23

Actual recruitment start date
2023-08-23, 1402/06/01
Actual recruitment end date
2024-02-12, 1402/11/23
Trial completion date
2024-06-19, 1403/03/30

Scientific title
Melatonin administered postoperatively lowers oxidative stress and inflammation and significantly recovers heart function in patients undergoing CABG Surgery

Public title
Effects of melatonin on patients after coronary artery bypass surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Intention of the patients to participate in the trial Patients on coronary artery bypass graft surgery Having no addiction to any drugs or alcohol Not having mental or psychological disorders Participants with the age between 30 to 70 years Absence of chronic diseases such as kidney, liver, digestive, bone diseases
Exclusion criteria:
The patient's refusal to continue cooperation after a period of taking the intervention The presence of special conditions after the operation, for example, the patient being unconscious and not being able to take the intervention The occurrence of any problems related to surgery, such as heart attack, cardiac arrhythmia, bleeding at the surgical site, myocardial damage, etc., which causes the patient's condition to become unstable.
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
The samples will be collected before and after the trial
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation method in this study will be permutated block randomization, where A and B represent the two intervention groups and C represents the control group. This method is performed by considering blocks of size 3 patients, so that the total number of 6 permutations is as follows: (A, B, C), (A, C, B), (B, A, C), (B, C, A), (C, A, B), (C, B, A). then, a number of 20 blocks will be randomly selected with replacement from these 6 block types. Finally, the desired list of 20 blocks of 3 (3 × 20 = 60 total number of samples) is generated, and the order of assignment to each of the samples participating in the study is determined. These steps are performed using computerized sequence-numbered codes that are given to the subjects in opaque envelopes at their first visit. Both the clinical team and participants are blinded from the time of randomization until the analysis is completed.
Blinding (investigator's opinion)
Double blinded
Blinding description
First, all melatonin and placebo capsules are prepared in the same shape and size and in packs of 60 for distribution to patients. The resveratrol and placebo packages are then labeled based on computer-generated codes (without indication of its content). Each of these codes is determined based on the sequence of random allocation of individuals to groups. The project manager, the only person who is aware of the codes and the order in which individuals are assigned to groups, is not involved in any of the evaluation and measurement of outcomes steps. On the other hand, the shape, size, and type of packaging of the resveratrol and placebo are exactly the same, so the patient and the outcome evaluator will not know the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Bushehr University of Medical Sciences
Street address
Moallem Street, Bushehr Medical University
City
Bushehr
Province
Boushehr
Postal code
7514633341
Approval date
2023-05-08, 1402/02/18
Ethics committee reference number
IR.BPUMS.REC.1402.060

Health conditions studied

1

Description of health condition studied
Diseases of the circulatory system
ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The heart function
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement
By echocardiography

2

Description
Diastolic blood pressure
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement
By sphygmomanometer, Mercury Type (Company: Microlife)

3

Description
Systolic blood pressure
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement
By sphygmomanometer, Mercury Type (Company: Microlife)

4

Description
CK-MB (creatine kinase MB)
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement
By reliable kits (By using spectrophotometry)

5

Description
LDH (lactate dehydrogenase)
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement
By reliable kits (By using spectrophotometry)

6

Description
TNF-α (tumor necrosis factor-α)
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement
By ELISA technique

7

Description
hs-CRP (High-sensitivity C-reactive Protein)
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement
By reliable kits (By using spectrophotometry)

8

Description
NO (Nitric oxide)
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement
By ELISA technique

9

Description
Total Antioxidant Capacity (TAC)
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement
By ELISA technique

10

Description
Malondialdehyde
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement
By reliable kits (By using spectrophotometry)

11

Description
Troponin T
Timepoint
Around 24 hours, before the start of melatonin consumption, and 12 to 24 hours after the period of melatonin consumption (60 days).
Method of measurement

By ELISA technique

Secondary outcomes

1

Description
Alanine aminotransferase (ALT)
Timepoint
Around 24 hours, before the start of melatonin consumption, and 24 to 72 hours after the period of 60 days of melatonin consumption
Method of measurement
By biochemistry auto analyzer- spectrophotometer

2

Description
Aspartate aminotransferase (AST)
Timepoint
Around 24 hours, before the start of melatonin consumption, and 24 to 72 hours after the period of 60 days of melatonin consumption
Method of measurement
By biochemistry auto analyzer- spectrophotometer

3

Description
Alkaline phosphatase (ALP)
Timepoint
Around 24 hours before the start of melatonin consumption, and 24 to 72 hours after the period of melatonin consumption(60 days) .
Method of measurement
By biochemistry auto analyzer- spectrophotometer

4

Description
Blood Urea Nitrogen
Timepoint
Around 24 hours before the start of melatonin consumption, and 24 to 72 hours after the period of melatonin consumption(60 days).
Method of measurement
By biochemistry auto analyzer- spectrophotometer

5

Description
Creatinine (Cr)
Timepoint
Around 24 hours before the start of melatonin consumption, and 24 to 72 hours after the period of melatonin consumption(60 days).
Method of measurement
By biochemistry auto analyzer- spectrophotometer

6

Description
Low density lipids (LDL)
Timepoint
Around 24 hours before the start of melatonin consumption, and 24 to 72 hours after the period of melatonin consumption(60 days).
Method of measurement
By biochemistry auto analyzer- spectrophotometer

7

Description
High density lipid (HDL)
Timepoint
Around 24 hours before the start of melatonin consumption, and 24 to 72 hours after the period of melatonin consumption(60 days).
Method of measurement
By biochemistry auto analyzer- spectrophotometer

8

Description
Cholesterol
Timepoint
Around 24 hours before the start of melatonin consumption, and 24 to 72 hours after the period of melatonin consumption(60 days).
Method of measurement
By biochemistry auto analyzer- spectrophotometer

9

Description
Triglyceride (TG)
Timepoint
Around 24 hours before the start of melatonin consumption, and 24 to 72 hours after the period of melatonin consumption(60 days).
Method of measurement
By biochemistry auto analyzer- spectrophotometer

Intervention groups

1

Description
Control group: The placebo group (250 mg neutral micro cellulose capsules) will be given half an hour before sleep, and all the tests including heart function, and blood sampling, will be exactly like the melatonin intervention group. It will be done before and after the study.
Category
Placebo

2

Description
Intervention group: Melatonin (5 mg capsule) will be given once a night for half an hour before going to sleep, for 60 days.
Category
Prevention

3

Description
Intervention group: This group will be given melatonin (10 mg capsules) once a night for half an hour before going to sleep for 60 days.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Bushehr Heart Center
Full name of responsible person
Ali Movahed
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Akram Farhadi
Street address
Salmon Farsi Street, Department of Research, Bahmani, Bushehr University of Medical Sciences.
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Email
Researh@BPUMS.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Bushehr 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
Boushehr University of Medical Sciences
Full name of responsible person
Ali Movahed
Position
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Latest degree
Ph.D.
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
The Deputy of Research is responsible to provide the information and documents to the participants in the Trial

When the data will become available and for how long
After the trial was over and the results were analyzed, for a period of one year, access to the document is possible.

To whom data/document is available
The data and other documents of the study will be given to my colleagues at my University and other researchers and academic members from different universities worldwide.

Under which criteria data/document could be used
If the researcher wants the document to use in the following research. The patients who want to know about the results of the examination

From where data/document is obtainable
The main investigator responsible for the trial is to be referred for the results or any other documents. Dr Ali Movahed, Biochemistry Laboratory, School of Medicine, Moallem ST, Bushehr.Mobile Number: 09173711063

What processes are involved for a request to access data/document
The applicants should submit a request letter to the principal investigator, or a request from the deputy of research. Then, the request will be assessed by these authorities and the right files and documents will be submitted to the requester for a period of one or two weeks.

Comments