

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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- α , 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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+98 77 3332 4044

Email address

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 permuted 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 ($3 \times 20 = 60$ 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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Research@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

Academic Member

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries

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Boushehr University of Medical Sciences

Full name of responsible person

Ali Movahed

Position

Academic Member

Latest degree

Ph.D.

Other areas of specialty/work

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

Boushehr University of Medical Sciences

Full name of responsible person

Ali Movahed

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)**

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