Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of melatonin on cardiac biomarkers after coronary artery bypass graft (CABG) surger: á pilot clinical trial

Protocol summary

Study aim

The goal of this randomized clinical trial is evaluating the effect of melatonin in cardiac biomarkers after coronary artery bypass graft (CABG).

Design

In the pilot randomized controlled trial, 100 patients undergoing coronary artery bypass grafting(CABG) will be randomly divided into two groups of Melatonin or placebo. Randomization will be done according to computerised random number generator.

Settings and conduct

100 patients undergoing coronary artery bypass grafting (CABG) in Buali-sina hospital in Qazvin, Iran, will be randomly divided into two groups of Melatonin or placebo. Participant and Investigator will be blinded to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 80 years old patients who are candidates for coronary artery bypass graft; Informed consent to participate in the study; Exclusion criteria: Taking anticonvulsants - antidepressants drugs; History of coronary artery bypass graft; Emergency Coronary Artery Bypass Grafting; Ejection Fraction ˂ 30.

Intervention groups

Patients will be randomly divided into two groups. In the melatonin group: We will prescribe 3 milligram melatonin on the night before and the morning of surgery and after surgery, 3 milligram melatonin before of night's sleep for three days. In the control group: Placebo will be prescribed on the night before and the morning of surgery and after surgery, before of night's sleep for three days.

Main outcome variables

ESR; CRP; CPK-MB; Troponin I; Arrhythmia; The number of days spent in hospital after surgery and Length of Stay for Critical Care Admissions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141006019417N2**
Registration date: **2018-11-30, 1397/09/09**
Registration timing: **prospective**

Last update: **2018-11-30, 1397/09/09**
Update count: **0**

Registration date

2018-11-30, 1397/09/09

Registrant information

Name

Nahid Nasseh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3332 8627

Email address

nnaseh@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin on cardiac biomarkers after coronary artery bypass graft (CABG) surger: ā pilot clinical trial

Public title
The effect of melatonin on Cardiac Enzymes after Cardiac surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18 to 80 years old patients who are candidates for coronary artery bypass graft; Informed consent to participate in the study.
Exclusion criteria:
Taking anticonvulsants - antidepressants drugs; History of coronary artery bypass graft; Emergency Coronary Artery Bypass Grafting; Ejection Fraction ˂ 30; Severe pulmonary disease; Non-sinus rhythm heart before surgery; Having a pacemaker; Liver disease; Simultaneously valvular heart surgery.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are randomly assigned to one of two study groups with the help of Random number generation software and receive the same group intervention.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and care providers are unaware of the allocation of study groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Deputy for research, Shahid Beheshti Ave, Qazvin, Iran.
City
Qazvin
Province
Qazvin
Postal code
3419759811
Approval date
2018-05-29, 1397/03/08
Ethics committee reference number
IR.QUMS.REC.1397.054

Health conditions studied

1

Description of health condition studied
coronary artery bypass graft (CABG) surgery
ICD-10 code
T82.9
ICD-10 code description
Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description
Biomarkers(Erythrocyte Sediman Rate, C-Reactive Protein, Troponin I & CPK-MB)
Timepoint
On six hours after entering the ICU and the second & third day after surgery
Method of measurement
Laboratory kits

Secondary outcomes

1

Description
Arrhythmia
Timepoint
Length of Stay for Critical Care Admissions
Method of measurement
Patient file

2

Description
Length of Stay for Critical Care Admissions
Timepoint
Total number of days the ICU
Method of measurement
Patient file

3

Description

The number of days spent in hospital after breast cancer surgery

Timepoint

Discharge day from hospital

Method of measurement

Patient file

Intervention groups

1

Description

Intervention group: In the melatonin group: We will prescribe 3 milligram melatonin on the night before and the morning of surgery and after surgery, 3 milligram melatonin before of night's sleep for three days.

Category

Treatment - Drugs

2

Description

Control group: Placebo will be prescribed on the night before and the morning of surgery and after surgery, before of night's sleep for three days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

BuAli Sina Hospital

Full name of responsible person

Nahid Nasseh

Street address

BuAli Sina Hospital., BuAli Ave., Qazvin town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Saeedeh Shiravandi

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific

inquiries

Contact

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Person responsible for updating data

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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
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