

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effect of melatonin on cardiac biomarkers after coronary artery bypass graft (CABG) surgery: a 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 $\leq$ 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: â pilot clinical trial		Street address Deputy for research, Shahid Beheshti Ave, Qazvin, Iran.	
Public title	The effect of melatonin on Cardiac Enzymes after Cardiac surgery	City Qazvin	
		Province Qazvin	
Purpose	Treatment	Postal code 3419759811	
Inclusion/Exclusion criteria		Approval date 2018-05-29, 1397/03/08	
		Ethics committee reference number IR.QUMS.REC.1397.054	
Inclusion criteria: 18 to 80 years old patients who are candidates for coronary artery bypass graft; Informed consent to participate in the study.		Health conditions studied <u>1</u> 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	
Exclusion criteria: Taking anticonvulsants - antidepressants drugs; History of coronary artery bypass graft; Emergency Coronary Artery Bypass Grafting; Ejection Fraction $\leq$ 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	Primary outcomes <u>1</u> 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	
Gender	Both		
Phase	3	Secondary outcomes <u>1</u> Description Arrhythmia Timepoint Length of Stay for Critical Care Admissions Method of measurement Patient file	
Groups that have been masked - Participant - Care provider			
Sample size	Target sample size: 100	<u>2</u> Description Length of Stay for Critical Care Admissions Timepoint Total number of days the ICU Method of measurement Patient file	
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.	3 Description	
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			
<u>1</u> Ethics committee Name of ethics committee Ethics committee of Qazvin University of Medical Sciences			

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

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Full name of responsible person

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Dept. of research., Shahid Beheshti, Ave., Qazvin., IRAN

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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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inquiries

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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