Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Evaluating the effect of melatonin on the prevention of postoperative atrial fibrillation and acute kidney and injury (AKI) following coronary artery bypass grafting (CABG) surgery

Protocol summary

Study aim

Evaluating the effect of melatonin on the prevention of postoperative atrial fibrillation and acute kidney and injury (AKI) following coronary artery bypass grafting (CABG) surgery

Design

In this study, 70 patients who are candidates for coronary artery bypass grafting surgery and referred to Dr Masih Daneshvari Hospital in Tehran are enrolled in the study. Participants are randomly divided into intervention and control groups.

Settings and conduct

Place of study: Dr Masih Daneshvari Hospital, How to do the study: 70 patients who are candidates for coronary artery bypass grafting surgery are randomly divided into two intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who undergo coronary artery bypass grafting at Dr Masih Daneshvari Hospital are randomly enrolled in the study. Exclusion criteria :a need for valvular surgery along with CABG surgery, history of any supraventricular arrhythmias, history of taking any antiarrhythmic agents except for beta blockers, history of epilepsy or seizure disorders, history of sleep pattern disorders, history of taking any drug affecting sleep pattern including benzodiazepines, history of autoimmune disorders, chronic hepatic failure, Chronic kidney disease or patients with Glomerular Filtration Rate of lower than 30 ml/min, history of taking anti inflammatory agents within 2 weeks of admission except for statins, patients undergoing CABG surgery emergently, patients receiving magnesium

Intervention groups

In the drug group, patients will receive 12 mg of sublingual melatonin the evening before and the morning before surgery. The control group does not receive the drug.

Main outcome variables

Incidence of atrial fibrillation; increasing of hs-CRP biomarker, ECG abnormalities , Incidence of acute kidney injury; Increasing of Creatinine biomarker

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N11**
Registration date: **2018-12-02, 1397/09/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-12-02, 1397/09/11**
Update count: **0**

Registration date

2018-12-02, 1397/09/11

Registrant information

Name
Farzaneh Dastan
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 912 270 5933
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-03, 1397/01/14

Expected recruitment end date

2019-04-03, 1398/01/14

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of melatonin on the prevention of postoperative atrial fibrillation and acute kidney and injury (AKI) following coronary artery bypass grafting (CABG) surgery

Public title
Evaluating the effect of melatonin on the prevention of postoperative atrial fibrillation and acute kidney and injury following open heart surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
patients who are candidates for elective CABG surgery in in a tertiary referral center
Exclusion criteria:
a need for valvular surgery along with CABG surgery history of any supraventricular arrhythmias history of taking any antiarrhythmic agents except for beta blockers,calcium channel blockers and cardiac glycosides history of epilepsy or seizure disorders history of cerebrovascular disorders history of sleep pattern disorders history of taking any drug affecting sleep pattern including benzodiazepines, antidepressants,antipsychotics, dopamin agonists and beta agonists history of autoimmune disorders chronic hepatic failure (liver enzymes rises more than 3 times the upper limit of normal) Chronic kidney disease (Stage IV & V) or patients with Glomerular Filtration Rate of lower than 30 ml/min history of taking anti inflammatory agents within 2 weeks of admission except for statins patients undergoing CABG surgery emergently patients receiving magnesium
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
More than 1 sample in each individual
Number of samples in each individual: **6**
plasma sample
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization method using table of random numbers is applied to the study population. Unit of randomization is individual. Even and odd numbers are chosen for the case and the control group, respectively. Numbered drug containers are applied for allocation concealment.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences ,Pharmacy Faculty
Street address
Intersection of Niyayesh Highway, Valieasr St., Shahid Beheshti University of Medical Sciences, Faculty of Pharmacy
City
Tehran
Province
Tehran
Postal code
141556153
Approval date
2018-07-01, 1397/04/10
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1397.066

Health conditions studied

1

Description of health condition studied
Atrial fibrillation
ICD-10 code
148.9
ICD-10 code description
Atrial fibrillation and atrial flutter, unspecified

2

Description of health condition studied
Acute kidney injury
ICD-10 code
N99.9
ICD-10 code description
Postprocedural disorder of genitourinary system, unspecified

Primary outcomes

1

Description
Creatinine plasma LEVEL
Timepoint
Before surgery, first, second, third, fourth and fifth day after surgery
Method of measurement
ELISA

2

Description
hs-CRP plasma LEVEL
Timepoint
Before surgery and 24 hours after surgery
Method of measurement
ELISA

3

Description
Incidence of atrial fibrillation
Timepoint
After surgery until 7 days
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Incidence of cardiac inflammation and injury
Timepoint
Before and 24 hours after surgery
Method of measurement
Measuring the amount of CK-MB and Troponin biomarker elevation in plasma sample by their kits

Intervention groups

1

Description
Intervention group: Administration of 12 mg sublingual melatonin tablets the night before and one hour before surgery.
Category
Prevention

2

Description
Control group: will not receive the drug
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr Masih Daneshvari Hospital
Full name of responsible person
Farzaneh Dastan
Street address
Masih Daneshvari Hospital, Darabad Street
City
Tehran
Province
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Postal code
1956944413
Phone
+98 21 2712 3000
Fax
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nima Naderi
Street address
Shahid Beheshti Faculty of Pharmacy, Niayesh Highway, Valiasr Ave, Tehran, Iran
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1991953381
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pr_pharmacy@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Saghar Barati

Position
Resident of Clinical pharmacy

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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Ṣhahid Beheshti Faculty of Pharmacy, Niayesh Highway, Valiasr Ave, Tehran, Iran

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Contact

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Position
Assisstant Professor, Clinical Pharmacy Specialist

Latest degree
Specialist

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Person responsible for updating data

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

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All of the information and knowledge achieved from this clinical trial will be published as an article.

When the data will become available and for how long
About 6 months after publication of the results.

To whom data/document is available
All of people have access to the information.

Under which criteria data/document could be used
In order to use the same drug for the specific indication in the clinical wards or to use the data for designing another relevant study

From where data/document is obtainable
The information are accessible via e-mail address and phone number: sgh_brt68@yahoo.com 09124236623

What processes are involved for a request to access data/document
After the end of trial, the information will be sent for a journal as a manuscript. the manuscript will be reviewed and after that, it will be published as a paper if the journal accepts the manuscript.

Comments