

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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)

##### Phone

+98 912 270 5933

##### Email address

f\_dastan@sbmu.ac.ir

##### 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 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, dopamine 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

Tehran

#### Postal code

1956944413

#### Phone

+98 21 2712 3000

#### Fax

#### Email

F\_dastan@sbmu.ac.ir

## 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

#### City

Tehran

#### Province

Tehran

#### Postal code

1991953381

#### Phone

+98 21 8820 0118

#### Email

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

**Street address**

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

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+98 21 8820 0118

**Email**

sgh\_brt68@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Farzaneh Dastan

**Position**

Assistant Professor, Clinical Pharmacy Specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for updating data

### 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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## 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**