

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of melatonin on cognitive function, after coronary artery bypass grafting surgery.

#### Protocol summary

##### Study aim

To evaluate the effect of melatonin on cognitive function, after coronary artery bypass grafting surgery.

##### Design

Double blind randomized clinical trial

##### Settings and conduct

50 patients undergoing coronary artery bypass grafting are divided into two groups. Patients in the first group received 10 mg melatonin 4 weeks before surgery, 2 days after surgery and patients in the second group received placebo. The patients will be evaluated by cognitive function tests 4 weeks before surgery, 2 days after surgery and 6 weeks after melatonin administration.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 40-75 years; Patients who are undergoing elective Cardio pulmonary artery bypass grafting. Exclusion criteria: Acute recent Myocardial Infarction (less than 3 month); Emergency operation; Re-operation; Concomitant renal insufficiency; Immunologic disorders; Concomitant cerebrovascular disease; prior stroke; severe pulmonary disease ; Ejection Fraction < 45%; ASA > 3; Current anticoagulation therapy with warfarin; concomitant cardiac surgery; Non sinus ECG; Hepatic insufficiency; Alcohol abuse; Regular medication with Benzodiazepines and opioid; Psychiatric disorders; Dementia; Pregnancy; breast feeding; Any infection less than 4 weeks ago; corticosteroid therapy since 1 month ago; Pump time more than 90 min; Peripheral vascular disease; Renal dysfunction; aortic atheromatosis .

##### Intervention groups

Intervention group: Patients received two oral capsules of melatonin 5 mg daily (Super Natural ,Canada) four weeks prior to surgery and up to two days after surgery. control group: patients received two oral placebo capsules daily made by Shiraz School of pharmacy at the same time periods.

##### Main outcome variables

Cognitive function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141009019470N77**

Registration date: **2019-03-03, 1397/12/12**

Registration timing: **prospective**

Last update: **2019-08-13, 1398/05/22**

Update count: **1**

##### Registration date

2019-03-03, 1397/12/12

##### Registrant information

##### Name

Farzaneh Masihi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4270

##### Email address

masihif@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-11, 1397/12/20

##### Expected recruitment end date

2019-07-25, 1398/05/03

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of melatonin on cognitive function, after coronary artery bypass grafting surgery.

**Public title**

The effect of melatonin on cognitive function, after coronary artery bypass grafting surgery.

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients aged 40-75 years Patients who are undergoing elective Cardio pulmonary artery bypass grafting.

**Exclusion criteria:**

Acute recent Myocardial Infarction (less than 3 month)  
Aortic atheromatosis Renal dysfunction; Peripheral vascular disease; Pump time more than 90 min;  
Corticosteroid therapy since 1 month ago; infection less than 4 weeks ago; Breast feeding Pregnancy; Dementia;  
Psychiatric disorders Using Benzodiazepines and opioid;  
Alcohol abuse Hepatic insufficiency Non sinus ECG;  
Concomitant cardiac surgery; Anticoagulation therapy with warfarin ASA higher than 3 Ejection Fraction less than 45% Severe pulmonary disease Cerebrovascular disease Immunologic disorders Re-operation Emergency operation

**Age**

From **40 years** old to **75 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The medicine or placebo are provided by a nurse who is aware of the study groups to the nurse who is unaware of the study groups and responsible for prescribing the medicine. Due to the complete similarity of the drug and placebo, the responsible nurse, the patient and the assessor are also not aware of the type of drug or placebo.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Approval date**

2017-08-26, 1396/06/04

**Ethics committee reference number**

IR.SUMS.MED.REC.1396.40

**Health conditions studied****1****Description of health condition studied**

Coronary Artery Bypass Grafting Surgery.

**ICD-10 code**

I25.1

**ICD-10 code description**

Atherosclerotic heart disease of native coronary artery

**Primary outcomes****1****Description**

Cognitive function

**Timepoint**

4 weeks before surgery, 2 days after surgery and 6 weeks after melatonin administration.

**Method of measurement**

Cognitive function Test

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Patients received two oral capsules of melatonin 5 mg daily made by (Super Natural ,Canada) from four weeks prior to surgery and up to two days after surgery..

**Category**

Prevention

## 2

### Description

Control group: Patients received two oral placebo capsules daily made by Shiraz School of pharmacy from four weeks prior to surgery and up to two days after surgery.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Namazi Hospital

##### Full name of responsible person

Kambiz Zohori

##### Street address

Namazi Hospital, Namazi Square

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3647 4270

##### Email

namazi@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Younes Ghasemi

##### Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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sacrc@sums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Kambiz Zohori

##### Position

Physician/cardiac anesthesia fellowship

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Reza Jouybar

##### Position

Cardio-anesthesiologist

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Anesthesiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Farzaneh Masihi  
**Position**  
BS in anesthesia/English Consultant  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Others  
**Street address**  
5th floor, Mohammad Rasoul Allah Research Tower,  
Khalili Street  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**

## 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

No - There is not a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### Data Dictionary

Not applicable