

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Feb 2026

### The effect of melatonin on interleukin 6 & interleukin 9 in coronary artery bypass grafting surgery

#### Protocol summary

##### Study aim

To investigate the effect of Melatonin on serum level of interleukin 6 and interleukin 9 in patients undergoing coronary artery bypass grafting(CABG).

##### Design

Randomized triple blinded clinical trial.

##### Settings and conduct

42 patients undergoing coronary artery bypass grafting(CABG) in Namazi hospital, Shiraz, Iran randomly divided into two groups of Melatonin or placebo. In the Melatonin group patients receive 10 mg Melatonin every night two weeks before the operation and patients in the placebo group received placebo every night two weeks before the operation. For evaluating serum level of IL-6 and IL-9 in the both groups 4 venous blood samples take from patients (two weeks before administration of melatonin, in the operating room before induction of anesthesia, 6 hours after declamping in the ICU and 48 hours after off pump), samples will have tested with human Th cytokine panel (13-plex), biolegend, USA by "bead-based assay" method & the level of interleukins in different phases: the effect of melatonin on inflammatory factors level will compare in case and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 42 Patients who are candidate for elective CABG with age between 40-75 years old and ASA class <III; pump time less than 90 min; graft number between 2 to 6. Exclusion criteria: pregnancy and breast feeding; local or systemic infection; hyper sensitivity; redo surgery; surgery during last 6 months; collagen vascular disease; immunosuppressive disease; heart failure with ejection fraction less than 35%; recent cardiovascular event; un controlled HTN; renal failure; liver failure; alcohol abuser; malignancy; simultaneously valvular heart surgery.

##### Intervention groups

In the Melatonin group patients receive 10 mg Melatonin every night two weeks before the operation and patients in the placebo group received placebo every night two

weeks before the operation.

##### Main outcome variables

serum level of interleukin 6 and interleukin 9

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141009019470N72**

Registration date: **2018-03-06, 1396/12/15**

Registration timing: **prospective**

Last update: **2018-03-06, 1396/12/15**

Update count: **0**

##### Registration date

2018-03-06, 1396/12/15

##### 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

2018-04-04, 1397/01/15

##### Expected recruitment end date

2018-08-06, 1397/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of melatonin on interleukin 6 & interleukin 9 in coronary artery bypass grafting surgery

**Public title**  
The effect of melatonin on interleukin 6 & interleukin 9 in coronary artery bypass grafting surgery

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients who are candidate for elective CABG age between 40-75 years old ASA class <III pump time less than 90 min; graft number between 2 to 6  
**Exclusion criteria:**  
pregnancy local or systemic infection hyper sensitivity redo surgery surgery during last 6 months collagen vascular disease immunosuppressive disease heart failure with ejection fraction less than 35% recent cardiovascular event renal failure alcohol abuser simultaneously valvular heart surgery uncontrolled HTN liver failure breast feeding

**Age**  
From **40 years** old to **70 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**  
Target sample size: **42**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
www.randomization.com

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
patient, accessor and observer are blinded to the study.

**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

2010-09-23, 1389/07/01

## Ethics committee reference number

IR.SUMS.REC.1396.16

## Health conditions studied

### 1

#### Description of health condition studied

Coronary Artery Bypass Surgery

#### ICD-10 code

I25.1

#### ICD-10 code description

Atherosclerotic heart disease of native coronary artery

## Primary outcomes

### 1

#### Description

serum level of interleukin 6 and interleukin 9

#### Timepoint

two weeks before administration of melatonin, in the operating room before induction of anesthesia, 6 hours after declamping in the ICU and 48 hours after off pump

#### Method of measurement

venous blood samples

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: patients receive 10 mg Melatonin every night two weeks before the operation.

#### Category

Prevention

### 2

#### Description

Control group: patients in the placebo group received placebo every night two weeks before the operation.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Namazi Hoptioal

**Full name of responsible person**

Mahtab Setoodeh

**Street address**

Namazi Hoptioal, Namazi Square

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**Province**

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**Postal code**

7134844119

**Phone**

+98 71 3647 4270

**Email**

mahtab.setoodeh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Seed Basir Hashemi

**Street address**

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

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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**

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**

Mahtab Setoodeh

**Position**

Anesthesiology resident/physician

**Latest degree**

Medical doctor

**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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joybarr@sums.ac.ir

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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**

MS in english teaching ,BS in anesthesia/English  
Consultant

**Latest degree**

Master

**Other areas of specialty/work****Street address**

5th floor, Mohammad Rasul Allah Research Tower,  
Khalili Street

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**Postal code**

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**Phone**

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**Fax****Email**

masihifarzaneh@yahoo.com

**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Its against our policy.

**Study Protocol**

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

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable