

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of melatonin on inflammatory cytokines in patients undergoing coronary artery bypass graft surgery

#### Protocol summary

##### Study aim

The effect of melatonin on inflammatory cytokines in patients undergoing coronary artery bypass graft surgery

##### 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 interleukin 17A & interleukin 17F and interleukin 21 in the both groups 4 venous blood samples taken 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

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; uncontrolled 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

##### Main outcome variables

Serum level inflammatory cytokines

#### General information

##### Reason for update

Changing the title of the study its became more general

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141009019470N73**

Registration date: **2018-03-07, 1396/12/16**

Registration timing: **prospective**

Last update: **2020-01-10, 1398/10/20**

Update count: **1**

##### Registration date

2018-03-07, 1396/12/16

##### 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 inflammatory cytokines in patients undergoing coronary artery bypass graft surgery

## Public title

The effect of melatonin on inflammatory cytokines in patients undergoing coronary artery bypass graft surgery

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

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; uncontrolled HTN; renal failure; liver failure; alcohol abuser; malignancy; simultaneously valvular heart surgery.

## 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**

More than 1 sample in each individual

Number of samples in each individual: **1**

For assessing serum level of interleukin 17A & interleukin 17F and interleukin 21 in patients blood sample will be taken.

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## 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

2017-12-26, 1396/10/05

## Ethics committee reference number

IR.SUMS.MED.REC.1396.20

## 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 Inflammatory cytokines

#### 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 in the placebo group received placebo 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**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Namazi Hospital

**Full name of responsible person**

Marzieh Ghasemi

**Street address**

Namazi Hospital, Namazi Square

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Shiraz

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7134844119

**Phone**

+98 71 3647 4270

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mrymghasemi1989dec@gmail.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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masihifarzaneh@yahoo.com

**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**

Marzieh Ghasemi

**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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## 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**

Others

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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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable