

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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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

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Person responsible for scientific inquiries

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Reza Jouybar

Position

Cardio-anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

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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**

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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