

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

The Effect of Melatonin on interleukin 13 and interleukin 22 in patients undergoing Coronary Artery Bypass Graft Surgery

Protocol summary

Study aim

Evaluation the effect of Melatonin on interleukin 13 and interleukin 22 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 randomly divided into two groups of Melatonin or placebo.

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 13 and interleukin 22

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N71**

Registration date: **2018-02-24, 1396/12/05**

Registration timing: **prospective**

Last update: **2018-02-24, 1396/12/05**

Update count: **0**

Registration date

2018-02-24, 1396/12/05

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 13 and interleukin 22 in patients undergoing Coronary Artery Bypass Graft Surgery

Public title

The Effect of Melatonin on interleukin in patients undergoing Coronary Artery Bypass Graft Surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
 En 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. Pump time less than 90 min; graft number between 2 to 6. 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 **75 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
 Patients were randomized according to the charts which was derived from www.randomization.com site.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 The participants, researcher and the Data and Safety Monitoring Board 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
 2017-09-23, 1396/07/01

Ethics committee reference number
 IR .SUMS.MED.REC.1396.17

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 13

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

2

Description

serum level of interleukin 22

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: 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
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital
Full name of responsible person
Ahad Izadpanah
Street address
Namazi Hospital, 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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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
Ahad Izadpanah
Position
Anesthesiology resident/physician
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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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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5th floor, Mohammad Rasoul Allah Research Tower,
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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

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