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)

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+98 71 3647 4270

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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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7134844119

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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
Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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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
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