Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of melatonin on cognitive function, after coronary artery bypass grafting surgery.

Protocol summary

Study aim
To evaluate the effect of melatonin on cognitive function, after coronary artery bypass grafting surgery.

Design
Double blind randomized clinical trial

Settings and conduct
50 patients undergoing coronary artery bypass grafting are divided into two groups. Patients in the first group received 10 mg melatonin 4 weeks before surgery, 2 days after surgery and patients in the second group received placebo.The patients will be evaluated by cognitive function tests 4 weeks before surgery, 2 days after surgery and 6 weeks after melatonin administration.

Participants/Inclusion and exclusion criteria
Inclusion criteria: aged 40-75 years; Patients who are undergoing elective Cardio pulmonary artery bypass grafting. Exclusion criteria: Acute recent Myocardial Infarction (less than 3 month); Emergency operation; Re-operation; Concomitant renal insufficiency; Immunologic disorders; Concomitant cerebrovascular disease; prior stroke; severe pulmonary disease ; Ejection Fraction< 45%; ASA> 3; Current anticoagulation therapy with warfarin; concomitant cardiac surgery; Non sinus ECG; Hepatic insufficiency; Alcohol abuse; Regular medication with Benzodiazepines and opioid; Psychiatric disorders; Dementia; Pregnancy; breast feeding; Any infection less than 4 weeks ago; corticosteroid therapy since 1 month ago; Pump time more than 90 min; Peripheral vascular disease; Renal dysfunction; aortic atheromatosis .

Intervention groups
Intervention group: Patients received two oral capsules of melatonin 5 mg daily (Super Natural ,Canada)four weeks prior to surgery and up to two days after surgery. control group: patients received two oral placebo capsules daily made by Shiraz School of pharmacy at the same time periods.

Main outcome variables
Cognitive function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141009019470N77**
Registration date: **2019-03-03, 1397/12/12**
Registration timing: **prospective**

Last update: **2019-08-13, 1398/05/22**
Update count: **1**

Registration date
2019-03-03, 1397/12/12

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
2019-03-11, 1397/12/20

Expected recruitment end date
2019-07-25, 1398/05/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of melatonin on cognitive function, after coronary artery bypass grafting surgery.

Public title
The effect of melatonin on cognitive function, after coronary artery bypass grafting surgery.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 40-75 years Patients who are undergoing elective Cardio pulmonary artery bypass grafting.
Exclusion criteria:
Acute recent Myocardial Infarction (less than 3 month) Aortic atheromatosis Renal dysfunction; Peripheral vascular disease; Pump time more than 90 min; Corticosteroid therapy since 1 month ago; infection less than 4 weeks ago; Breast feeding Pregnancy; Dementia; Psychiatric disorders Using Benzodiazepines and opioid; Alcohol abuse Hepatic insufficiency Non sinus ECG; Concomitant cardiac surgery; Anticoagulation therapy with warfarin ASA higher than 3 Ejection Fraction less than 45% Severe pulmonary disease Cerebrovascular disease Immunologic disorders Re-operation Emergency operation
Age
From **40 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
The medicine or placebo are provided by a nurse who is aware of the study groups to the nurse who is unaware of the study groups and responsible for prescribing the medicine. Due to the complete similarity of the drug and placebo, the responsible nurse, the patient and the assessor are also not aware of the type of drug or placebo.
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
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Fars
Postal code
7134844119
Approval date
2017-08-26, 1396/06/04
Ethics committee reference number
IR.SUMS.MED.REC.1396.40

Health conditions studied

1

Description of health condition studied
Coronary Artery Bypass Grafting Surgery.
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Cognitive function
Timepoint
4 weeks before surgery,2 days after surgery and 6 weeks after melatonin administration.
Method of measurement
Cognitive function Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients received two oral capsules of melatonin 5 mg daily made by (Super Natural ,Canada)from four weeks prior to surgery and up to two days after surgery..
Category
Prevention

2

Description
Control group:Patients received two oral placebo capsules daily made by Shiraz School of pharmacy from four weeks prior to surgery and up to two days after surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Kambiz Zohori
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Kambiz Zohori
Position
Physician/cardiac anesthesia fellowship
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Person responsible for updating data

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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
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable