Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of melatonin in post operative sleep disorder (POSD) acccording to their Pittsburg sleep quallity index , and cardiac enzymes after coronary artery bypass graft (CABG)

Protocol summary

Summary

The goal of this randomized clinical trial is evaluating the effect of melatonin in post operative sleep disorder (POSD) and cardiac enzymes after coronary artery bypass graft (CABG). More than 50% of patients who undergone CABG, will experience sleep disturbance. Melatonin can improve sleep quality beside its antioxidant effects and cardiovascular benefits. 100 patients, who are candidates for CABG, will be randomized to be in control or melatonin group. patients in melatonin group will receive 3 mg melatonin every night, during the time of hospitalization. Their sleep quality will be assessed by the Pittsburgh Sleep Quality Index, at the time of admission, after CABG, and before discharge. The antioxidant and cardiovascular protective effects of melatonin will be assessed by measuring Troponin, CKMB, and CRP at 6, 12, and 24 hours after blood reperfusion during the CABG.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303148698N11**
Registration date: **2013-04-05, 1392/01/16**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-04-05, 1392/01/16

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-05-01, 1392/02/11

Expected recruitment end date

2014-10-01, 1393/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of melatonin in post operative sleep disorder (POSD) acccording to their Pittsburg sleep quallity index , and cardiac enzymes after coronary artery bypass graft (CABG)

Public title

Effect of melatonin in post operative sleep disorder (POSD), and cardiac biomarckers after coronary artery bypass graft (CABG)

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: 1. Patients who are candidates for CABG procedure. exclusion criteria: 2. Patients who have been used hypnotic drugs for their sleep disorder.

Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran Heart Center
Street address
Kargar shomali street, Tehran Heart Center
City
Tehran
Postal code
Approval date
2013-03-13, 1391/12/23
Ethics committee reference number
755

Health conditions studied

1

Description of health condition studied
patients who are candidate for coronary artery bypass surgery
ICD-10 code
T82.9
ICD-10 code description
Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description
Sleep quality
Timepoint
first day of admision, after CABG, At the time of discharge
Method of measurement
PSQI score

2

Description
Cardiac biomarckers (CKMB, Troponin, CRP)
Timepoint
At 6, 12 and 24 hours after blood reperfusion in CABG
Method of measurement
Labratuary kits

Secondary outcomes

1

Description
anxiety
Timepoint
At the time of admision, after CABG, and before discharge
Method of measurement
Hemilton

Intervention groups

1

Description
tab melatonin 3 mg before sleep for 7 nights
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran heart center
Full name of responsible person
Mehrnoush Dianatkhah
Street address
Kargar shomali street, jalal crossroad, Tehran heart center
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran university of medical sience
Full name of responsible person
Fatemeh saeedi

Street address
16'th azar street, Tehran university of medical sience
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran university of medical sience
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Tehran university of medical sience
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assistant, professor
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Person responsible for updating data

Contact
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Full name of responsible person
Mehrnoush Dianatkhah
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Other areas of specialty/work
Street address
City
Postal code
Phone
00
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty