

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Effect of melatonin in post operative sleep disorder (POSD) according to their Pittsburg sleep quality 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

Azita Hajhossein Talasaz

Name of organization / entity

Department of Clinical Pharmacy, Faculty of

Pharmacy, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66954709

Email address

atalasaz@razi.tums.ac.ir

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) according to their Pittsburg sleep quality 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 admission, after CABG, At the time of discharge

Method of measurement

PSQI score

2**Description**

Cardiac biomarkers (CKMB, Troponin, CRP)

Timepoint

At 6, 12 and 24 hours after blood reperfusion in CABG

Method of measurement

Labratory kits

Secondary outcomes**1****Description**

anxiety

Timepoint

At the time of admission, 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

Mehnoush Dianatkah

Street address

Kargar shomali street, jalal crossroad, Tehran heart center

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran university of medical science

Full name of responsible person

Fatemeh saeedi

Street address

16'th azar street, Tehran university of medical science

City

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 science

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****Name of organization / entity**

Tehran university of medical science

Full name of responsible person

Mehrnoush dianatkah

Position

resident of pharmacotherapy

Other areas of specialty/work**Street address**

16th of azar street, Tehran university of medical science

City

Tehran

Postal code**Phone**

+98 913 201 1241

Fax**Email**

mehrnoush_d@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran heart center, Tehran university of medical science

science

Full name of responsible person

Azita Haj Hossein Talasaz, padideh ghaeli

Position

assistant, professor

Other areas of specialty/work**Street address**

Tehran,kargar shomali street, jalal crossroad, Tehran heart center

City

Tehran

Postal code**Phone**

00982188029600, 00982166954709

Fax**Email**

atalasaz@razi.tums.ac.ir , mmppg@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity****Full name of responsible person**

Mehrnoush Dianatkah

Position**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*