

# 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)

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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) 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**

Labraturary 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

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resident of pharmacotherapy

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Tehran heart center, Tehran university of medical

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**Full name of responsible person**

Azita Haj Hossein Talasaz, padideh ghaeli

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assistant, professor

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Mehrnoush Dianatkah

**Position****Other areas of specialty/work****Street address****City****Postal code****Phone**

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**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*