

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of melatonin tablets compared to lorazepam tablets on circadian rhythm of sleep and serum level of leptin and cortisol and melatonin in CABG patients admitted in heart ICU ward of Mousavi hospital, Zanjan

Protocol summary

Summary

In this double blinds clinical trial, 80 patients who are candidate for coronary artery bypass grafts in ICU open heart surgery ward get to study serially if they will be satisfied to cooperate in this study. Inclusion criteria: age older than 18 years old; GCS ≥ 10 ; stable hemodynamic state; no dependence on the ventilator. Exclusion criteria : pregnancy; sleep disorder; convulsion; neuropsychiatric disorders; blindness and deafness; liver and kidney disorders; CHF; gastroparesia; drugs that reduce melatonin effect; sensitivity to melatonin; worsening of overall health; earlier discharge from the sixth day. After personal information questionnaire (proposal index) completion for all patients, the patients will be assigned to two groups randomly that includes melatonin tablet receivers and lorazepam tablet receivers. In the morning of hospitalization day, 5 cc venous blood samples will be taken from all the patients in this study to assess blood levels of leptin, melatonin and cortisol. The patients of two groups will take 3mg melatonin tablet for four nights at 21 o'clock of every night (for 40 patients of first group from second day to fifth stay day) and 2 mg lorazepam tablet for four nights at 21 o'clock of every night (for 40 patients of second group from second day to fifth stay day). After four nights, 5 cc venous blood samples will take from all patients to measure serum levels of leptin, melatonin and cortisol. Standard Sleep Disorders Questionnaire (SSS) is used to assess quality of sleep at former night of operation and fourth night of hospitalization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082523760N1**
Registration date: **2016-10-25, 1395/08/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-25, 1395/08/04

Registrant information

Name

Mohammad Reza Jamshidi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 912 334 6346

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanjan University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-02-17, 1395/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of melatonin tablets compared to lorazepam tablets on circadian rhythm of sleep and serum level of

leptin and cortisol and melatonin in CABG patients admitted in heart ICU ward of Mousavi hospital, Zanjan

Public title

The effect of melatonin tablet on sleep disorders in patients in cardiac surgery intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age older than 18 years old; GCS \geq 10; stable hemodynamic state; no dependence on the ventilator. Exclusion criteria: pregnancy; sleep disorder; convulsion; neuropsychiatric disorders; blindness and deafness; liver and kidney disorders; CHF; gastroparesia; drugs that reduce melatonin effect; sensitivity to melatonin; worsening of overall health; earlier discharge from the sixth day.

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Double blind clinical study (patients and researcher).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zanjan University of Medical Sciences

Street address

Zanjan University of Medical Sciences, Azadi blvd.

City

Zanjan

Postal code

Approval date

2015-07-28, 1394/05/06

Ethics committee reference number

IR.ZUMS.REC.1394.91

Health conditions studied

1

Description of health condition studied

Sleep disorders

ICD-10 code

G47.2

ICD-10 code description

Circadian rhythm sleep disorders

Primary outcomes

1

Description

Sleep disorders

Timepoint

First nights and the fourth night stay

Method of measurement

Stanford Sleep Scale Questionnaire (SSS Questionnaire)

2

Description

Serum leptin level

Timepoint

Second and fifth day of hospitalization

Method of measurement

Germany laboratory elisa kits

3

Description

Serum melatonin level

Timepoint

Second and fifth day of hospitalization

Method of measurement

Germany laboratory elisa kits

4

Description

Serum cortisol level

Timepoint

Second and fifth day of hospitalization

Method of measurement

Germany laboratory elisa kits

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 40 patient in Melatonin group will take 3 mg melatonin tablet for four nights

Category

Treatment - Drugs

2

Description

Intervention group 2: 40 patient in Lorazepam group will take 2 mg lorazepam tablet for four nights.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

ICU ward, Mousavi hospital

Full name of responsible person

Dr Afagh Anjomshoaa

Street address

Mousavi hospital, Gavazang road

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

Street address

Zanjan University of Medical Sciences, Azadi blvd.

City

Zanjan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan University of Medical Sciences

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

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Afagh Anjomshoaa

Position

MD

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Jamshidi

Position

Fellowship of cardiac anesthesias

Other areas of specialty/work

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Full name of responsible person

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Position

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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