

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the effect of Quetiapine and Alprazolam on sleep in patients who complain of insomnia after CABG (coronary artery bypass graft) surgery

Protocol summary

Study aim

Comparison of the effect of Alprazolam and Quetiapine on sleep of patients who complain of insomnia after coronary artery bypass graft surgery

Design

Double blinded clinical trial with control group that has two parallel group with sample size of 64 persons

Settings and conduct

Drugs were packed in groups A and B. Drugs packs were delivered to the nurses of heart surgery ward of chamran hospital in Isfahan. Group A drugs were prescribed for patients who were entered to ward at saturday, monday and wednesday. Group B drugs were prescribed for patients who are entered to ward at sunday, tuesday and thursday. So the physician (main researcher), nurses and patients dont know the type of drugs. The executive manager and the collector of information know type of patients drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients should undergo CABG and complain of insomnia after surgery. Exclusion criteria: Unstable medical conditions, History of psychological disease, Dementia, Acute narrow angle glaucoma, Hypersensitivity to drug.

Intervention groups

32 patients receive half of TRANQOPINE 25mg tablet, every nights 30 minutes before sleep, from 3 days after surgery until 14 days after surgery. 32 patients receive one ALPRAZOLAM 0.5 mg tablet from abidi company, every nights 30 minutes before sleep, from 3 days after surgery untile 14 days after surgery.

Main outcome variables

Insomnia Score according to (ISI) questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160716028945N4**
Registration date: **2018-11-07, 1397/08/16**
Registration timing: **retrospective**

Last update: **2018-11-07, 1397/08/16**

Update count: **0**

Registration date

2018-11-07, 1397/08/16

Registrant information

Name

Amir Mirmohammadsadeghi

Name of organization / entity

Isfahan Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3260 0961

Email address

am_sadeghi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-03-18, 1396/12/27

Actual recruitment start date

2017-06-22, 1396/04/01

Actual recruitment end date

2018-06-19, 1397/03/29

Trial completion date

2018-06-19, 1397/03/29

Scientific title

Comparison of the effect of Quetiapine and Alprazolam on sleep in patients who complain of insomnia after CABG (coronary artery bypass graft) surgery

Public title

Comparison of the effect of Quetiapine and Alprazolam on insomnia after coronary artery bypass graft surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient should undergo CABG and complain of insomnia after surgery

Exclusion criteria:

Unstable medical conditions
History of psychological disease
Dementia
Acute narrow angle glaucoma
Hypersensitivity to drug

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **64**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs were packed in groups A and B. Drugs packs were delivered to the nurses of heart surgery ward. Group A drugs were prescribed for patients who were entered to ward at Saturday, Monday and Wednesday. Group B drugs were prescribed for patients who are entered to ward at Sunday, Tuesday and Thursday. So the physician (main researcher), nurses and patients don't know the type of drugs. The executive manager and the collector of information know type of patients' drugs.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Science

City

Isfahan

Province

Isfahan

Postal code

73461-81746

Approval date

2017-02-01, 1395/11/13

Ethics committee reference number

IR.MUI.REC.1396.3.191

Health conditions studied

1

Description of health condition studied

Insomnia

ICD-10 code

G47.09

ICD-10 code description

Other insomnia

Primary outcomes

1

Description

Insomnia score according to (ISI) questionnaire

Timepoint

Three days after surgery (before intervention) and fourteen days after surgery

Method of measurement

(ISI) insomnia questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 32 patients receive half of TRANQOPINE 25mg tablet, every night 30 minutes before sleep, from 3 days after surgery until 14 days after surgery.

Category

Treatment - Drugs

2

Description

Control group: 32 patients receive a ALPRAZOLAM 0.5 mg tablet from Abidi company, every night 30 minutes before sleep, from 3 days after surgery until 14 days after surgery.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Iman Nariman

Street address

Chamran Hospital, Salman Farsi st.

City

Isfahan

Province

Isfahan

Postal code

81661-73414

Phone

+98 31 3260 0961

Email

iman.narimani0@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmad Movahedian Atar

Street address

Isfahan University of Medical Sciences, Hezar Jerib st.

City

Isfahan

Province

Isfahan

Postal code

73461-81746

Phone

+98 31 3668 8138

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Amir Mirmohammadsadeghi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiac Surgery

Street address

Chamran Hospital, Salman Farsi st.

City

Isfahan

Province

Isfahan

Postal code

81661-73414

Phone

+98 31 3260 0961

Fax

Email

am_sadeghi@med.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because of secondary data analyze

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available