

# 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 until 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 University 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.

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**Phone**

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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

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**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**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Amir Mirmohammadsadeghi

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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