# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Investigating the effect of Quetiapine on delirium in patients undergoing coronary artery bypass graft surgery; a double-blind clinical trial

## Protocol summary

**Study aim**

Investigating the effect of quetiapine on delirium in patients undergoing CABG surgery

**Design**

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial of 82 patients. For randomization, a random sequence created in blocks of four using the site http://www.graphpad. com/quickcalcs/index.cfm will be used.

**Settings and conduct**

This study will be conducted as a clinical trial in Heshmat Hospital in Rasht. After explaining the purpose and method of the research, informed consent will be obtained. Patients will be randomly divided into intervention and control groups. The medicine will be given to the patient by a nurse who is not in the study. The drug will be administered orally or through a nasogastric/intestinal tube. Delirium examination of patients in the ICU will be evaluated by a trained anesthesiologist on a daily basis, from the day of surgery until the patient's discharge from the ICU. The delirium assessment criteria will be the CAM-ICU scale (Confusion Assessment Method for the ICU). This study will be double-blinded. The patient and the evaluator (anesthetist assistant) will be unaware of the treatment groups. The anesthesiologist of the ICU team is aware of the groups so that in case of complications, therapeutic interventions can be performed.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Elective patients , 35-85 years, ASA Class II,III, GCS 15. Exclusion criteria: liver and kidney failure, history of mental illness and cognitive behavioral problems.

**Intervention groups**

Intervention group:12.5 mg of oral quetiapine , the first dose on the morning of surgery, before surgery (quetiapine 25 mg tablet), and then every 12 hours until 48 hours after surgery, for a total of 4 doses. Control group: will not receive any drug prophylaxis.

**Main outcome variables**

Occurrence of delirium during ICU hospitalization

## General information

**Reason for update**

1- Editing information related to Inclusion criteria(GCS 15, ASA Class II,III): GCS 15 is appropriate because the assessment of postoperative delirium in patients entering the study must be clinically fully conscious. ASA Class II,III is appropriate because ASA Class IV is for patients undergoing emergency surgery, but this study was conducted in patients who were candidates for elective coronary artery bypass grafting. 2- In the intervention section, the method of administering quetiapine was described in more detail and revised. Also, the time period for examining delirium in postoperative patients was revised to 3 days after surgery, as patients are hospitalized in the ICU for a maximum of three days after surgery.

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20130525013456N7**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **prospective**

Last update: **2025-09-25, 1404/07/03**
Update count: **2**

**Registration date**

2023-08-21, 1402/05/30

**Registrant information**

**Name**

Abbas Sedighinejad

**Name of organization / entity**

Guilan University of Medical Sciences

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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2023-08-23, 1402/06/01
**Expected recruitment end date**
2024-03-20, 1403/01/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the effect of Quetiapine on delirium in patients undergoing coronary artery bypass graft surgery; a double-blind clinical trial

**Public title**
effect of Quetiapine on delirium in patients undergoing coronary artery bypass graft surgery
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Elective patients who are candidates for coronary artery bypass surgery 85- 35 years American Society of Anesthesiologists (ASA) II,III GCS 15 to be fully alert and able to communicate
**Exclusion criteria:**
Liver and kidney failure Emergency surgery Confirmation of delirium before ICU admission Patients with a history of mental illness and cognitive behavioral problems before surgery Allergy to quetiapine and its ingredients
**Age**
From **35 years** old to **85 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Investigator

**Sample size**
Target sample size: **82**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients will be assigned to two groups: quetiapine and control by a random sequence created in blocks of four by using the site http://www.graphpad.com/quickcalcs/index.cfm, which was created by a statistical consultant in a ratio of 1:1 and will be performed by a nurse who is not aware of the goals of the study.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
In this double-blind study, the drug will be given to the patient by a nurse who is not participating in the study, and the delirium of patients in the ICU will be evaluated and recorded by a trained anesthesia assistant who is unaware of the treatment groups. In this way, the patient and the person evaluating and recording the information (trained anesthesia assistant) will be unaware of the treatment groups. The anesthesiologist of the ICU team will be aware of the groups to take the necessary actions in case of complications.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Guilan University of Medical Sciences
**Street address**
Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street,Rasht
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**Province**
Guilan
**Postal code**
4144654839
**Approval date**
2023-07-26, 1402/05/04
**Ethics committee reference number**
IR.GUMS.REC.1402.242

## Health conditions studied

**1**

**Description of health condition studied**
Determining the effect of Quetiapine on delirium in patients undergoing CABG surgery
**ICD-10 code**
F05.8
**ICD-10 code description**
Postoperative delirium

## Primary outcomes

**1**

**Description**
Occurrence of delirium during ICU hospitalization

**Timepoint**
Daily from the day of surgery until the patient is discharged from the ICU (for 3 days)
**Method of measurement**
CAM- ICU (Confusion Assessment Method for the ICU)

## Secondary outcomes

### 1

**Description**
Side effects of the drug
**Timepoint**
Daily
**Method of measurement**
Observation

## Intervention groups

### 1

**Description**
Intervention group: The group will receive 12.5 mg of oral quetiapine, the first dose on the morning of surgery, then every 12 hours until 48 hours after surgery (25 mg quetiapine tablets manufactured by Fatek Shimi Pars Company - Iran), for a total of 4 doses, by a nurse who is not in the study. In patients with a nasogastric/intestinal tube, the patient's dose of quetiapine will be crushed, mixed with 10 ml of water and administered through the nasogastric/intestinal tube. The feeding tubes will be flushed with 30 ml of sterile water after each dose of quetiapine according to hospital protocol.
**Category**
Prevention

### 2

**Description**
Control group: The control group will not have any medical prophylaxis.
**Category**
Prevention

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Heshmat Hospital
**Full name of responsible person**
Abbas Sedighinejad
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## Sponsors / Funding sources

### 1

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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Rasht 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**
Academic

## Person responsible for general inquiries

**Contact**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**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