

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 911 132 5712

Email address	Double blinded
a_sedighinejad@gums.ac.ir	Blinding description
Recruitment status	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.
Recruitment complete	Placebo
Funding source	Not used
Expected recruitment start date	Assignment
2023-08-23, 1402/06/01	Parallel
Expected recruitment end date	Other design features
2024-03-20, 1403/01/01	
Actual recruitment start date	Secondary Ids
empty	empty
Actual recruitment end date	Ethics committees
empty	1
Trial completion date	Ethics committee
empty	Name of ethics committee
Scientific title	Ethics committee of Guilan University of Medical Sciences
Investigating the effect of Quetiapine on delirium in patients undergoing coronary artery bypass graft surgery; a double-blind clinical trial	Street address
Public title	Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street,Rasht
effect of Quetiapine on delirium in patients undergoing coronary artery bypass graft surgery	City
Purpose	Rasht
Prevention	Province
Inclusion/Exclusion criteria	Guilan
Inclusion criteria:	Postal code
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	4144654839
Exclusion criteria:	Approval date
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	2023-07-26, 1402/05/04
Age	Ethics committee reference number
From 35 years old to 85 years old	IR.GUMS.REC.1402.242
Gender	Health conditions studied
Both	1
Phase	Description of health condition studied
3	Determining the effect of Quetiapine on delirium in patients undergoing CABG surgery
Groups that have been masked	ICD-10 code
- Participant - Investigator	F05.8
Sample size	ICD-10 code description
Target sample size: 82	Postoperative delirium
Randomization (investigator's opinion)	Primary outcomes
Randomized	1
Randomization description	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.	Occurrence of delirium during ICU hospitalization
Blinding (investigator's opinion)	

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

Street address

Fifteenth Khordad Street

City

Rasht

Province

Guilan

Postal code

4165432678

Phone

+98 911 132 5712

Email

heshmat@gums.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Naghipoor

Street address

Vice Chancellor for research, Shahid Siadati Avenue, Namjoo Street, Rasht

City

Rasht

Province

Guilan

Postal code

6694941446

Phone

+98 13 3333 5821

Email

naghi@gums.ac.ir

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****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Abbas Sedighinejad

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Research Center, Alzahra Hospital, Namjoo Street, Rasht, Iran

City
Rasht
Province
Guilan
Postal code
4144654839
Phone
+98 13 3332 9524
Fax
+98 13 1323 3448
Email
A_sedighinejad@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Abbas Sedighinejad
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Anesthesiology Research Center, Alzahra Hospital,
Namjoo Street, Rasht, Iran
City
Rasht
Province
Guilan
Postal code
4144654839
Phone
+98 13 3332 9524
Fax
+98 13 1323 3448
Email
A_sedighinejad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Mohadese Ahmadi
Position
Research Expert/(MSc) English
Latest degree
Master
Other areas of specialty/work
Research Expert
Street address
Anesthesiology Reseach Center, Alzahra Hospital,
Namjoo Street
City
Rasht
Province
Guilan
Postal code
4144654839
Phone
+98 13 3336 9328
Email
p.ahmadi2311@gmail.com

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