

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effect of quetiapine on the prevention of delirium in patients admitted to the intensive care unit (randomized clinical trial study)

Protocol summary

Study aim

Investigating the effect of quetiapine on the prevention of delirium in patients admitted to the intensive care unit (randomized clinical trial study)

Design

This study is a randomized controlled trial with two groups. The sample size is determined through the allocation of random blocks based on the national code. The intervention group will be given quetiapine and will be monitored for three days for the occurrence of delirium and its severity. Nikham scale is used to measure the severity of delirium.

Settings and conduct

Randomization will be used to form two equal groups. The severity of delirium will be measured using Neecham's statistics. The study will compare the severity of delirium between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ICU hospitalization, age over 18, patient consent, no alcohol addiction, healthy vision and hearing (or corrected with glasses/hearing aids), no psychotropic drug use. Exclusion criteria: head trauma, long QT, encephalopathy, systolic blood pressure above 140, diastolic blood pressure above 90, tachycardia (beats >100/min), history of seizures, quetiapine susceptibility, intubation. Exclusion from study: patient transfer, sedative drug infusion, BP drop (>25% of baseline), death before 72 hours, QT prolongation, tachycardia (beats >100/min), neutropenia <1500.

Intervention groups

Intervention group: Patients who are given quetiapine at a dose of 25 mg every 8 hours and trained for the occurrence of delirium. Control group: Patients who receive standard treatment for any complications and side effects, but do not receive quetiapine.

Main outcome variables

Delirium Frequency, Delirium Severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180520039739N5**

Registration date: **2023-06-20, 1402/03/30**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name

Mohammadreza Habibzadeh siahroodkolaee

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-24, 1402/03/03

Expected recruitment end date

2023-06-24, 1402/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of quetiapine on the prevention of delirium in patients admitted to the intensive care unit (randomized clinical trial study)

Public title

Effect of Quetiapine in Preventing Delirium in ICU Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalization in the intensive care unit Age over 18 years Patient satisfaction No alcohol addiction Healthy vision and hearing or elimination of vision and hearing defects by using glasses and hearing aids No use of psychoactive drugs

Exclusion criteria:

head trauma QT prolongation Encephalopathy Basal systolic blood pressure above 140 Basal diastolic blood pressure above 90 Tachycardia (beats more than 100 per minute) History of seizures Hypersensitivity to quetiapine intubated patient

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

Then the patients are divided into two groups using the permuted block randomization computer method. This method involves dividing participants into blocks and randomly assigning them to treatment groups in each block. This helps ensure balanced allocation and minimizes bias in study findings.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The triple-blind aspect of the trial refers to the fact that neither the patient, the person responsible for examining delirium, nor the statistical analyst has knowledge of which group the patient belongs to. This means that all parties involved in the study are unaware of the specific treatment or intervention being administered to each patient. This blinding process is crucial in reducing the potential for bias and ensuring the integrity of the results. The way the study is conducted is that there is an external observer in this study who assigns generic names such as A and B to the drug (intervention) and placebo (control). The participant/researcher/statistical consultant knows who is in group A and who is in group B. But no one knows whether group A is intervention or

control. Finally, after the study and interpretation of the results by the statistician, the observer reveals to which group each name belonged

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee in Biomedical Researches, Faculty of Medicine, Isfahan University of Medical Sciences

Street address

Faculty of medicine, Isfahan university of medical science, Hezar Jerib Avenue, Isfahan, Iran.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-02-04, 1400/11/15

Ethics committee reference number

IR.MUI.MED.REC.1400.781

Health conditions studied

1

Description of health condition studied

patient admitted to the intensive care unit

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes

1

Description

Delirium Frequency

Timepoint

every 8 hours

Method of measurement

The number of episodes of delirium observed in an 8-hour period. This variable measures how often delusions occur in each group And it is measured using the Neecham criterion.

2

Description

Severity of delirium

Timepoint

every 8 hours

Method of measurement

The intensity or severity of delirium symptoms experienced by participants was measured using the Neecham scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention in this study involves administering quetiapine, a medication commonly used to treat psychiatric disorders. The dose of quetiapine given is 25 mg, which is administered every 8 hours for three days. The patients are trained by a nurse or a doctor to report any occurrence of delirium at regular intervals (every 8 hours) for three days, and the occurrence of delirium, its intensity, and duration are recorded by the relevant nurse using the Neecham Anesthesia scale. If any complications arise due to the use of the medication, it is immediately discontinued, and standard treatment is provided to manage the side effects. These side effects include a drop in blood pressure by more than 25% of baseline pressure, tachycardia (heartbeats more than 100 per minute), and neutropenia (reduction in white blood cell count) less than 1500.

Category

Treatment - Drugs

2

Description

Control group: the control group is the group of patients who did not receive the intervention (quetiapine). They are used as a comparison group to evaluate the effectiveness of the intervention group (the group that received quetiapine). The control group is randomly selected and receives the same care and attention as the intervention group except for the administration of the drug.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital, Isfahan

Full name of responsible person

Marzieh Mirtavosi

Street address

Al-Zahra Hospital, Hezar Jerib Ave, Isfahan, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammadreza Habibzadeh siahroodkolaee

Position

Assictant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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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