Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

A comparative study of the effect of citalopram in the prevention of delirium in intubated patients without brain damage in Labafinejad Hospital ICU

Protocol summary

Study aim

Investigating the effect of citalopram on the prevention of agitation and delirium in intubated patients hospitalized in ICU

Design

Randomization: Patients will be enrolled sequentially from 1 to 62. Then using a random number table, patients who get an odd number will be assigned to the intervention group and those who get an even number will be placed in the control group. This allows random allocation into the two arms. Sample Size: 62 patients (31 in each group) Trial Phase: This is a Phase 2-3clinical trial.

Settings and conduct

This study is a clinical trial that will be conducted on ventilator-connected patients suffering from internal diseases and sepsis who are hospitalized in the ICU of Labafini Nejad Hospital, the patients will be included in the study as odd or even numbers. The drug group and those with an even number will be placed in the placebo group. The patients who are placed in the drug group will be gavage of escitalopram tablets daily, and the other group will be gavage of placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age greater than 18 years / acute and intubated patients admitted to the intensive care unit / patients admitted to the intensive care unit without brain injury / not currently taking any other antidepressant / not pregnant or lactating / willing to sign Informed consent form Study exclusion criteria: Known hypersensitivity to es-citalopram or any of its components/Active suicidal thoughts or behavior/Severe liver or kidney failure/Uncontrolled arrhythmias/ Uncontrolled bleeding

Intervention groups

intervention group :will receive 10mg of escitalopram daily. The escitalopram will be administered orally in the form of a tablet. Patients will take one 10mg tablet of escitalopram by mouth daily. Control group: Patients randomly allocated to the control group will receive a placebo

Main outcome variables

Delirium and Agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190215042716N6**
Registration date: **2023-12-26, 1402/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-26, 1402/10/05**
Update count: **0**

Registration date

2023-12-26, 1402/10/05

Registrant information

Name

navid shafigh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8801 3378

Email address

n.shafigh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-03, 1402/09/12

Expected recruitment end date

2024-07-20, 1403/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of citalopram in the prevention of delirium in intubated patients without brain damage in Labafinejad Hospital ICU

Public title

A comparative study of the effect of citalopram in the prevention of delirium in intubated patients without brain damage in Labafinejad Hospital ICU

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age□18 years old Acute patients hospitalized in the intensive care unit (ICU under mechanical ventilation with a ventilator) Patients hospitalized in the intensive care unit without brain damage Is not currently taking any other antidepressants Not pregnant or lactating Willing to sign an informed consent form

Exclusion criteria:

Known hypersensitivity to es-citalopram or any of its components Active suicidal thoughts or behavior Severe liver or kidney failure Uncontrolled arrhythmias Active bleeding History of mania or hypomania Severe personality disorders Current substance abuse or dependence Participation in other clinical trials

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be included in the study as even or odd numbers. That is, from numbers 1 to 62, all the people with odd numbers will be in the drug group and those with even numbers will be in the placebo group. We will enroll patients into the study sequentially and assign them numbers from 1 to 62 based on order of enrollment. Patients with odd numbers (1, 3, 5, etc.) will be placed in the treatment group. This group will receive 10mg of escitalopram daily via oral administration. Patients with even numbers (2, 4, 6, etc.) will be placed in the placebo group. This group will also receive an oral administration but will not receive the active drug. At the end of the study, we will compare the treatment effect between the two groups. This method allows for random allocation of patients into the two groups. The patients who are in the drug group will be given daily Citalopram 10 mg tablet will be gavage and will be gavage in the placebo group

Blinding (investigator's opinion)

Double blinded

Blinding description

The nurses will give the drugs of the 2 groups, which are completely matched in terms of shape, color and packaging, to the patients, and after that, the special care nurse, who has no knowledge of the received medicine, will collect the requested parameters of the patients, and then The information in two groups will be given to the data analyst and will be analyzed

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid beheshti University od Medical Sciences

Street address

Faculty of Medicine - Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2023-12-03, 1402/09/12

Ethics committee reference number

IR.SBMU.MSP.REC.1402.483

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

2

Description of health condition studied

Agitation

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes

1

Description

Agitation

Timepoint

3 hours after gavage of citalopram and placebo to intubated patients hospitalized in ICU for 14 days

Method of measurement

Richmond agitation sedation scale

2

Description

Delirium

Timepoint

3 hours after gavage of citalopram and placebo to intubated patients hospitalized in ICU for 14 days

Method of measurement

CAM_ICU score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patients randomly allocated to the intervention group will receive 10mg of escitalopram daily. The escitalopram will be administered orally in the form of a tablet. Patients will take one 10mg tablet of escitalopram by mouth once daily. This group is the active treatment group receiving the study medication escitalopram.Escitalopram is a selective serotonin reuptake inhibitor (SSRI) used to treat major depressive disorder and generalized anxiety disorder. It works by blocking the reabsorption of serotonin in the brain, which increases the level of serotonin available to improve mood and emotional state.The 10mg daily dose of escitalopram was selected as it is a common starting dose for this medication. Patients in the intervention group will come in to the study clinic once a day and be directly observed taking their 10mg dose of escitalopram tablets to ensure adherence. They will then be assessed for efficacy and side effects throughout the trial duration.

Category

Treatment - Drugs

2

Description

Control group: Patients randomly allocated to the control group will receive a placebo. The placebo will be in the form of a tablet similar to the escitalopram tablets but without any active ingredients. Similar to the intervention group, patients in the control group will also receive one oral tablet daily under direct observation. However, since the placebo contains no active drug, they do not actually receive an active treatment. Comparing this group to the intervention group will demonstrate the treatment effect of escitalopram.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinezhad Hospital

Full name of responsible person

Navid shafigh

Street address

9th Boostan, Pasdaran St.

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1956944413

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Lamc@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Navid Shafigh

Street address

Shahid Shahriari Square, Daneshjo Boulevard, Shahid Chamran Highway,

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n.shafigh@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Navid Shafigh

Position
Consultant

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
No. 15, 26th St., 27th Street, Kurdistan Highway, Tehran Town

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Consultant

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Subspecialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
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Navid Shafigh

Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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

Title and more details about the data/document
The whole potential data after being unidentifiable is published

When the data will become available and for how long
One year

To whom data/document is available
Medical Society

Under which criteria data/document could be used
Contributing to studies

From where data/document is obtainable

Email: n.shafigh@sbmu.ac.ir

What processes are involved for a request to access data/document

2 months

Comments