Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the efficacy and adverse effects of dexmedetomidine and haloperidol in reducing the symptoms of Deliriumin patients in Intensive Care Unit - A Randomized Clinical Trial.

Protocol summary

Study aim

Determining and comparing effects and side effects of using dexmedetomidine and haloperidol in reducing symptoms of delirium in patients of special care unit of Khurshid and Al-Zahra Hospital in Isfahan in2023

Design

The clinical trial has a control group,with parallel group,double-blind,randomized with table of random numbers,phase three on 64 randomly selected from127eligible to enter the study.Patients are divided to two groups random selected by lottery and randomizationed with table of random numbers.control group receives haloperidol and intervention group receives dexmedetomidine for three days,then severity of delirium in each group is evaluated by Richmond questionnaire

Settings and conduct

A double-blind randomized controlled clinical trial is conducted on patients aged above 18 in ICU patients of Khurshid and Al-Zahra Hospital in Isfahan who have delirium to compare the effect and side effects of using dexmedetomidine and haloperidol in reducing the symptoms of delirium.Concealment is done by a sealed envelope and doctors are given a table of coded numbers in advance and the patients are entered into the study in the order of the table numbers,concealment of groups and blind codes are kept in signed and sealed envelopes,and in this way,sample and researchers are blinded

Participants/Inclusion and exclusion criteria

Inclusion criteria:delirious patients based on criterias of DSM5 and having desired scores based on screening questionnaires mentioned Exclusion criteria:Delirious patients treated with other drugs

Intervention groups

patients randomly divided to two groups of 32people,in intervention group dexmedetomidine administered intravenously with starting dose of 0.5 µg/kg/hour and in control group,haloperidol administered intravenously 2mg/day

Main outcome variables

severity of delirium,drug side effects,average score of ICDSC and RASS

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221128056654N1**
Registration date: **2023-04-16, 1402/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-16, 1402/01/27**
Update count: **0**

Registration date

2023-04-16, 1402/01/27

Registrant information

Name

Ahmadreza Aghabozorgi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3222 0016

Email address

aghabozorgi.a@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and adverse effects of dexmedetomidine and haloperidol in reducing the symptoms of Deliriumin patients in Intensive Care Unit - A Randomized Clinical Trial.

Public title

Investigation of Dexmedetomidine and Haloperidol in Delirium symptoms in Intensive Care Unit patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are diagnosed with delirium based on DSM5 criteria. Patients who have not received non-pharmacological treatments to control symptoms. 5≤ICDSC و RASS≥+1 Not being intubated or extubated for more than 24 hours Hospitalization in ICU for non-surgical reasons

Exclusion criteria:

Patients who receive drugs other than dexmedetomidine or haloperidol for the treatment of delirium (such as other antipsychotics and midazolam) Receiving dexmedetomidine or haloperidol within 72 hours before entering the study Patients with a history of drug sensitivity to dexmedetomidine or haloperidol. Patients with a history of long QTc (<500 ms) Patients with dementia, Parkinson's, malignant neuroleptic syndrome, patients with a history of major psychiatric disorders such as bipolar and schizophrenia, addiction to various drugs and stimulants. Women during breastfeeding and pregnancy Unwillingness of the patient or family to participate in the study Severe forms of vision and hearing

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

The investigated samples will be divided into two groups using a simple randomization method. The selection of this randomization method is based on the sample size of the present study (less than 100 people) to ensure an equal number of people in each group. Individual randomization unit and random number table randomization tool. In order to hide the random allocation, sealed opaque envelopes with a random sequence are used in such a way that first the random sequence is created using the mentioned method, then based on the sample size of the research,A number of envelopes are prepared with aluminum envelopes (so that the contents of the envelopes are not clear) and each of the random sequences created is recorded on a card and the cards are placed inside the envelopes in order. In order to preserve the random sequence, on The outer surface of the envelopes is numbered in the same order.Finally, the lid of the envelopes is glued and placed in a box in order. At the time of registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes is opened in order and the assigned group is assigned to it. The participant will be revealed. The process of random allocation is carried out in such a way that one person will create the random sequence and the other person will check the participants in terms of entry and exit criteria and enroll them in the study and the person Third, it will assign the participants to groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study in such a way that the patient and the assistant who collects the information and fills the questionnaires are kept blind. Both drugs are used in the form of vials and intravenous injections in patients hospitalized in the intensive care unit, so the participant is not aware of the type of injected drug.

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. Hezar Jerib Street, Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Approval date

2022-06-15, 1401/03/25

Ethics committee reference number
IR.MUI.MED.REC.1401.253

Health conditions studied

1

Description of health condition studied
delirium
ICD-10 code
F05
ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
Mean score of ICDSC questionnaire
Timepoint
Intensive care Delirium Screening checklist (ICDSC) will be evaluated for daily delirium evaluation for up to 3 days.
Method of measurement
Intensive care Delirium Screening checklist (ICDSC)

2

Description
Mean SCORE OF RASS QUESTIONNAIRE
Timepoint
After the intervention, every hour to 6 hours, then every 1 hour to 3 days
Method of measurement
Richmond Agitation Sedation Scale (RASS)

Secondary outcomes

1

Description
Delirium intensity
Timepoint
From the time of intervention (drug prescription) daily for 3 days
Method of measurement
Patient's clinical status

2

Description
ICDSC and RASS questionnaires for patients at specified intervals and results were obtained.
Timepoint
Every one hour to six hours after starting the medicine and then continue every six hours to seventy two hours.
Method of measurement
Richmond Agitation Sedation Scale (RASS) scoring system and also Intensive care Delirium Screening checklist (ICDSC)

Intervention groups

1

Description
In the group receiving dexmedetomidine manufactured by Exir pharmaceutical company, the drug is administered intravenously with a starting dose of 0.5 µg/kg per hour. To achieve the effect of the drug, at least one hour of injection is required. Therefore, after one hour, the patient is evaluated through the RASS questionnaire, and if a score of zero is obtained, the drug is continued with the same dose for 72 hours, and the RASS questionnaire is administered every hour for 6 hours and then every 12 hours until the end of 72 hours from the start of the intervention. will be completed If after the injection with the initial dose, a score higher than zero is obtained in the RASS questionnaire, the injection is continued with a dose of 0.8 µg/kg per hour, and the assessment of the patient's condition is carried out in the same order as mentioned above.If the patient's agitation is not controlled with this dose (a score of zero in the RASS questionnaire means a suitable response to the treatment), in the next step, the drug is injected at a dose of 1.2 µg/kg per hour. If the agitation is not controlled with this dose, The result is considered as the ineffectiveness of the drug in controlling the patient's symptoms, and other drugs are used according to the patient's condition, and the delirium status of the patient is evaluated through the ICDSC questionnaire every day.
Category
Treatment - Drugs

2

Description
Intervention group: The group receiving haloperidol manufactured by Exir pharmaceutical company will start intravenously at a minimum dose of 2mg/day and will be injected up to a maximum dose of 6 mg/day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
AhmadReza Aghabozorgi
Street address
...
City
Isfahan
Province
Isfehan
Postal code
75731-81746
Phone

+98 38 3222 0016

Email

aghabozorgi.ahmadreza@gmail.com

2

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

AhmadReza Aghabozorgi

Street address

...

City

Isfahan

Province

Isfehan

Postal code

81458-33117

Phone

+98 31 3222 2127

Email

aghabozorgi.ahmadreza@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

AhmadReza Aghabozorgi

Street address

...

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

aghabozorgi.ahmadreza@gmail.com

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

AhmadReza Aghabozorgi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

....

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3668 0048

Email

aghabozorgi.ahmadreza@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ahmadreza Aghabozorgi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

Isfahan, Hazarjarib St

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3668 0048

Fax

Email

aghabozorgi.ahmadreza@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

AhmadReza Aghabozorgi

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
....

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Phone
+98 31 3668 0048

Email
aghabozorgi.ahmadreza@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Age, sex, treatment protocol, response to treatment, and answers to two ICDSC and RASS questionnaires can be accessed for each participant without mentioning personal information.

When the data will become available and for how long
Access has been started since 2024

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
By mentioning the source, it can be used for researchers.

From where data/document is obtainable
Dr Hajar Salimi Address: Khurshid Hospital, Department of Psychiatry Landline: 03132222475 Mobile phone: 09133285298 salimi85ha@gmail.com

What processes are involved for a request to access data/document
Sending an e-mail requesting access to information to the main presenter (Ms. Dr. Salimi)

Comments