Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of Olanzapine and Haloperidol and quetiapine on the Treatment of delirium in Intensive care unit (ICU) patients

Protocol summary

Study aim

The effect of olanzapine, haloperidol and quetiapine in the treatment of delirium in Intensive care unit (ICU) patients in Valiasr Hospital in Arak is compared.

Design

A Phase 3 parallel randomized double-blind clinical trial without a control group on 90 patients using three-group web randomization (www.graphpad.com)

Settings and conduct

This study will be performed in Valiasr Hospital and Amir Al-Momenin Hospital in Arak. In this way, 90 patients with delirium admitted to the intensive care unit will be randomly divided into three groups: haloperidol, olanzapine and quetiapine . In this study,drugs in the same shape, size and color will be prepared, so patients are not aware of the type of drug used and only the main performer is aware of the study groups and Clinical caregiver and intervention outcome assessor are not aware of the study groups and recognize them only on the basis of letters A, B and C.Patients will be treated for 10 days and the severity of the disease and the degree of relief of patients will be evaluated before the intervention and 3, 7 and 10 days after.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have been diagnosed with delirium by DSM V criteria and are over 18 years of age and have a brain injury. Exclusion criteria : Stroke, dementia, psychosis, pregnancy and lactation, QT interval more than 440 milliseconds

Intervention groups

Intervention group 1: haloperidol (Sobhan Daru Company - Iran) at a dose of 2.5 mg per day for up to 10 days
Intervention group 2: olanzapine (Sobhan Daru Company - Iran) at a dose of 2.5-10 mg per day for up to 10 days
Intervention group 3: quetiapine (Bakhtar Shimi-Iran Pharmaceutical Company) at a dose of 12.5 to 75 mg per day for up to 10 days

Main outcome variables

sedation, severity of illness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200927048852N1**
Registration date: **2020-10-13, 1399/07/22**
Registration timing: **prospective**

Last update: **2020-10-13, 1399/07/22**
Update count: **0**

Registration date

2020-10-13, 1399/07/22

Registrant information

Name

mohammad islamy

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3312 5311

Email address

pedramislamy1374@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Olanzapine and Haloperidol and quetiapine on the Treatment of delirium in Intensive care unit (ICU) patients

Public title
Comparison of olanzapine and haloperidol and quetiapine on delirium
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients who have been diagnosed with delirium by the 5th edition of Diagnostic and Statistical Manual of Mental Disorders (DSM-5) criteria and have suffered a brain injury
Exclusion criteria:
primary neurological diseases such as stroke, dementia, psychosis pregnancy and lactation modified QT interval more than 440 milliseconds
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Three-group web randomization (www.graphpad.com) was used to create a simple random sequence and to conceal random allocation, the SNOSE closed envelope method Will be used. a number of envelopes will be prepared and each of the random sequences created will be registered on a card and the cards will be placed inside the envelopes in order. In order to maintain a random sequence, envelopes are numbered in the same way on the outer surface. Finally, the letter envelopes are glued and placed inside the boxes, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants to study, one of the envelopes is opened in order and the assigned group of the participant is revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study is a double-blind clinical trial and the implementers of the project with the help of treatment staff will try to conduct the study without any bias according to the principles of the project. In this regard, only the main researcher is aware of the study groups and patients. He is not aware and as much as possible he tries to prepare drugs with the same shape, color and size and prescribe them according to the same principles and using a nasogastric tube. Also, the clinical caregiver and outcome assessor are not aware of the type of groups and identify patients based on groups A, B and C.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Payambar-e-azam Complex, Basij Sq., Sardash Townt
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2020-05-12, 1399/02/23
Ethics committee reference number
IR.ARAKMU.REC.1399.174

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
Sedation
Timepoint
Before the intervention and the third, seventh and tenth days after the intervention
Method of measurement
Richmond Agitation and Sedation Scale

2

Description
Illness severity
Timepoint
Before the intervention and the third, seventh and tenth days after the start of the intervention

Method of measurement
Acute Physiology and Chronic Health Evaluation II

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: In the first group, patients with delirium receive haloperidol (Sobhan Daru Company - Iran) at a dose of 2.5 mg per day, once daily and orally for 10 days until the end of the intervention.
Category
Treatment - Drugs

2

Description
Second intervention group: In the second group, patients with delirium receive olanzapine (Sobhan Daru Company - Iran) at a dose of 2.5 to 10 mg per day daily and orally until the end of the intervention for 10 days.
Category
Treatment - Drugs

3

Description
Third intervention group: In the third group, patients with delirium receive quetiapine (Bakhtar Shimi-Iran Pharmaceutical Company) at a dose of 12.5 to 75 mg daily and orally for 10 days until the end of the intervention.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Mohammad Eslami
Street address
Valiasr hospital, Valiasr Sq.
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Email
pr_valieasr@arakmu.ac.ir

2

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
Mohamad eslami
Street address
Basij Sq., Sardasht town
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3601
Email
it-amiralmomenin@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Payambar-e-azam Complex, Basij Sq., Sardash Townt
City
Arak
Province
Markazi
Postal code
3848176341
Phone
+98 86 3417 3639
Email
research@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Mohamad Eslami

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
School of Medicine, Payambar-e-azam Complex, Sardasht Town

City
Arak

Province
Markazi

Postal code
3848176341

Phone
+98 86 3417 3520

Email
daneshkadeha@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mohamad Eslami

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
School of Medicine, Payambar-e-azam Complex, Sardasht Tow

City
Arak

Province
Markazi

Postal code
3848176341

Phone
+98 86 3417 3520

Email
daneshkadeha@arakmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Mohamad Eslami

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

Street address
School of Medicine, Payambar-e-azam Complex, Sardasht Tow

City
Arak

Province
Markazi

Postal code
3848176341

Phone
+98 86 3417 3520

Email
daneshkadeha@arakmu.ac.ir

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