

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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)

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+98 86 3312 5311

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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		groups and identify patients based on groups A, B and C.	
Public title	Comparison of olanzapine and haloperidol and quetiapine on delirium	Placebo	Not used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria		Other design features	
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	Secondary Ids	
Exclusion criteria:	primary neurological diseases such as stroke, dementia, psychosis pregnancy and lactation modified QT interval more than 440 milliseconds	empty	
Age	From 18 years old	Ethics committees	
Gender	Both	1	
Phase	3	Ethics committee	
Groups that have been masked	- Participant - Care provider - Outcome assessor	Name of ethics committee	
Sample size	Target sample size: 90	Ethics committee of Arak University of Medical Sciences	
Randomization (investigator's opinion)	Randomized	Street address	
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.	Payambar-e-azam Complex, Basij Sq., Sardash Townt	
Blinding (investigator's opinion)	Double blinded	City	
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	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

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3814957558

Phone

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pr_valieasr@arakmu.ac.ir

2

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Mohamad eslami

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Basij Sq., Sardasht town

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Province

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Email

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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

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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

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Person responsible for scientific inquiries

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Position

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Latest degree

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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