

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison the effect of Olanzapine and Haloperidol on the treatment of delirium in ICU in Valiasr hospital

Protocol summary

Study aim

Evaluayion effect of Olanzapine and Haloperidol on the treatment of delirium in ICU in Valiasr hospital

Design

This study is clinical trial and double blind.50 patients with delirium in ICU in Valiasr Hospital in Arak will inter this study.We will divide patients in 2 groups by simple randomization.Groups are parallel.

Settings and conduct

This study is clinical trial and double blind.50 patients with delirium in ICU in Valiasr Hospital in Arak will inter this study.Outcome assessor and analyzer don't aware from grouping.We record sedation and illness severity.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Delirium detection ,age older than 18 years ,no pregnancy and breastfeeding ,insensitivity to Olanzapine and Haloperidol ,absence of QTC is greater than 440 milliseconds ,absence of a neurological disease such as stroke, dementia, psychosis ,having a urine catheter ,lack of mental disorder or disability disorder pre-admission Exclusion criteria:Patients who have more than 24 hours of coma and have a structural reason for their low level of consciousness, dissatisfaction

Intervention groups

Intervention group 1: We inject Haloperidol 2/5 milligram (maximum 40 milligram) intramuscular injection every 6 hours. Intervention group2: We inject 2/5 to 10 milligram Olanzapine orally (maximum 20 milligram).

Main outcome variables

sedation, illness severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N114**

Registration date: **2019-07-03, 1398/04/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-03, 1398/04/12**

Update count: **0**

Registration date

2019-07-03, 1398/04/12

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-05, 1397/10/15

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Olanzapine and Haloperidol on the treatment of delirium in ICU in Valiasr hospital

Public title

Comparison the effect of Olanzapine and Haloperidol on the treatment of delirium in ICU in Valiasr hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Delirium detection Age older than 18 years No pregnancy and breastfeeding Insensitivity to Olanzapine and Haloperidol Absence of QTc is greater than 440 milliseconds Absence of a neurological disease such as stroke, dementia, psychosis Having a urine catheter Lack of mental disorder or disability disorder pre-admission

Exclusion criteria:

Patients who have more than 24 hours of coma and have a structural reason for their low level of consciousness. Dissatisfaction

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random number table in division of groups in two groups A and B Randomization method: Simple randomization. Random unit: Individual. How to build sequences: First, we set the framework for our statistical society. We started from a table point in a row or column. Given the type of code in the row, we chose the same number of digits. After that, the numbers control the path. We noticed smaller numbers of the statistical community. We have to continue this work so that the number of samples is completed. Even numbers were used for intervention group and odd numbers were used for the control group. Allocation concealment: Numbered drug containers

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor. In order to blind the patients in the haloperidol group, the placebo tablet and we inject ampule of normal saline intramuscularly in the olanzapine group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar Azam Complex, Basij Squire, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2018-12-30, 1397/10/09

Ethics committee reference number

IR.ARAKMU.REC.1397.257

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

Every 8 hours

Method of measurement

Richmond agitation and sedation scale

2**Description**

Illness severity

Timepoint

In first and third day after the intervention

Method of measurement

APACHE II score

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: We inject Haloperidol 2/5 milligram (maximum 40 milligram) intramuscular injection every 6 hours.

Category

Treatment - Drugs

2**Description**

Intervention group 2: We inject 2/5 to 10 milligram Olanzapine orally (maximum 20 milligram).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr hospital

Full name of responsible person

Dr Behnam Mahmodie

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

mahmodie@arakmu.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

arjmandzadegan@arakmua.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

Dr Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alikamaliir@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Behnam Mahmodie

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

mahmodie@arakmu.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Atefeh Bighami

Position

Student of medicine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street addressPayambar Azam Complex, Basij square, Sardasht,
Arak**City**

Arak

Province

Markazi

Postal code

848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

doctorati73@gmail.com

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Mahmodie

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

They have to write letters to the professors and the university

Comments