Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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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 hallopridol 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 Squre, 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 squre, Shahid Shirodi street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
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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
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Person responsible for updating data

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Atefeh Bighami
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Student of medicine
Latest degree
Medical doctor
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General Practitioner
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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
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