Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Nov 2026

Comparison the Effect of Quetiapine and Haloperidol on the Treatment of delirium in ICU

Protocol summary

Study aim
Aim of this study is comparison the Effect of Quetiapine and Haloperidol on the Treatment of delirium in ICU in Valiasr hospital.

Design
This study is clinical trial and double blind. patients with delirium referred ICU in Valiasr hospital enter this study . 60 patients enter this study. We divide patients in 2 group randomly.

Settings and conduct
This study is clinical trial and double blind. patients with delirium referred ICU in Valiasr hospital enter this study . 60 patients enter this study. We divide patients in 2 group randomly.This study is double blind.Outcome elevator and participant are blind (double blind).Outcome elevator and participant don't aware from grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Delirium detection, more than 18 years exclusion criteria: Dissatisfaction

Intervention groups
We inject 2.5 milligram in day Haloperidol in first group. We inject 25 milligram Quetiapine twice in day in second group.

Main outcome variables
sedation, illness severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180911040998N1**
Registration date: **2018-10-31, 1397/08/09**
Registration timing: **registered_while_recruiting**

Last update: **2018-10-31, 1397/08/09**
Update count: **0**

Registration date
2018-10-31, 1397/08/09

Registrant information
Name
Alireza Toghra
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-04, 1396/11/15

Expected recruitment end date
2020-02-04, 1398/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the Effect of Quetiapine and Haloperidol on the Treatment of delirium in ICU

Public title
Comparison the Effect of Quetiapine and Haloperidol on the Treatment of delirium in ICU

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Delirium detection more than 18 years
Exclusion criteria:

Dissatisfaction

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is double blind.Outcome elevator and participant are blind (double blind).Outcome elevator and participant don't aware from grouping.The participants are not aware of group name that they are. The outcome evaluator don't knows the groups as A and B and is unaware of type of treatment in each group.

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

City
Arak

Province
Markazi

Postal code
848176941

Approval date
2018-01-21, 1396/11/01

Ethics committee reference number
IR.ARAKMU.REC.1396.286

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 day to end of intervention

Method of measurement
Richmond agitation and sedation scale

2

Description
Illness severity

Timepoint
1, 3, 7 and 10 day after start of intervention

Method of measurement
APACHE II

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: We inject 2.5 milligram in day Haloperidol in first group.

Category
Treatment - Drugs

2

Description
Intervention group2: We inject 25 milligram Quetiapine twice in day in second group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr hospital

Full name of responsible person
Dr Behnam Mahmudie

Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
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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
Assisstant professor
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Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Toghra
Position
student of medicine
Latest degree
Medical doctor
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General Practitioner
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Email
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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 Behnam Mahmudie

What processes are involved for a request to access data/document
They have to write letters to the professors and the university

Comments