

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 evaluator and participant are blind (double blind). Outcome evaluator 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

ar.toghra@arakmu.ac.ir

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 evaluator and participant are blind (double blind). Outcome evaluator and participant don't aware from grouping. The participants are not aware of group name that they are. The outcome evaluator don't know 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 square, 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

Dr Mohammad Arjmandzadegan

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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

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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

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Full name of responsible person

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Position

Assisstante professor

Latest degree

Subspecialist

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

Other areas of specialty/work

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