

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the Effectiveness of Haloperidol and quetiapine for delirium in the Emergency department and intensive Care Unit

Protocol summary

Study aim

Evaluation of the effectiveness of Haloperidol and quetiapine in Delirium

Design

This is a double blind randomized control trail with control group (parallel group). patients will be divided in to two 100 participants based on random table.

Settings and conduct

Patients who referred to Emem Reza hospital emergency department and intensive care unit with delirium will be enrolled the study, from the April to August 2018 .

Participant, care provider, outcome assessor and data analysts would be unaware of administered drug.

Participants/Inclusion and exclusion criteria

Patients diagnosed delirium aged more than 18 years based on Diagnostic and Statistical Manual of Mental Disorders (DSM-5) will enrolled the study. Long QTC interval syndrome and delirium syndrome occur because of alcohol withdrawal or benzodiazepines will be excluded

Intervention groups

first intervention group: 5 mg Haloperidol (IM) second intervention group: 25 mg quetiapine (oral)

Main outcome variables

Delirium severity score regard to Delirium Rating Scale-Revised-98 (DRS-R-98)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121231011956N10**

Registration date: **2018-04-21, 1397/02/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-21, 1397/02/01**

Update count: **0**

Registration date

2018-04-21, 1397/02/01

Registrant information

Name

Morteza Talebi Doluee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5312

Email address

talebidm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effectiveness of Haloperidol and quetiapine for delirium in the Emergency department and intensive Care Unit

Public title

Effectiveness of Haloperidol and quetiapine in delirium

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Delirium based on Diagnostic and Statistical Manual of Mental Disorders (DSM-5)

Exclusion criteria:

dementia alcohol withdrawal symptoms alcohol withdrawal symptoms benzodiazepine withdrawal symptoms long QTC syndrome

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant, Care provider, Outcome assessor and Data analyser would be unaware of administered drug.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

Street address

Imam Reza sq , Ebnesina ave.

City

Mashhad

Province

Razavi Khorasan

Postal code

1234567

Approval date

2017-08-02, 1396/05/11

Ethics committee reference number

IR.MUMS.fm.REC.1396.599

Health conditions studied**1****Description of health condition studied**

delirium

ICD-10 code

F05

ICD-10 code description

An etiologically nonspecific organic cerebral syndrome characterized by concurrent disturbances of consciousness and attention, perception, thinking, memory, psychomotor behaviour, emotion, and the sleep-wake schedule. The duration is variable and the deg

Primary outcomes**1****Description**

Delirium severity score regard to Delirium Rating Scale-Revised-98 (DRS-R-98)

Timepoint

dialy

Method of measurement

Delirium Rating Scale-Revised-98 (DRS-R-98) questioner

Secondary outcomes

empty

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

Intervention group: 25 mg quetiapine tablet will be administered orally for patients, single dose

Category

Treatment - Drugs

2**Description**

Intervention group: 5 mg haloperidol will be injected in gluteal muscle, single dose

Category

Treatment - Drugs

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

Department of emergency medicine , Imam Reza hospital

Full name of responsible person

Dr. Morteza Talebi

Street address

Imam Reza Hospital, Imam Reza Square, Ebne Sina Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
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Vice Chancellor for Research, Mashhad University of
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Morteza Talebi
Position
Emergency medicine specialist , assistant professor of
emergency medicine

Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
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Person responsible for updating data

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Phone

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Email

talebimd@mums.ac.ir

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

Data will be coded and will be shared.

When the data will become available and for how long

starting in January 2020

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

N/A

From where data/document is obtainable

Email Dr.Talebi.

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

email should be sent from an academic institutions and 2 months will be lasted from sending email and getting data.

Comments