Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Nov 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)
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+98 51 3852 5312
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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

City

Mashhad
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1234567
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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
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
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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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Web page address

Person responsible for updating data

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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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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