

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of efficacy of haloperidol and olanzapine in the treatment of delirium patient admitted in ICU

Protocol summary

Study aim

This study aimed to investigate the efficacy of olanzapine and haloperidol in the treatment of delirium in patients with ICU intoxication.

Design

36 patients with delirium are divided into two groups of 18 each. Each drug is randomly assigned double-blind and randomized to each group using blocking.

Settings and conduct

Patients with intoxication in the ICU of Loghman Hospital in Tehran, for whom delirium is diagnosed. The placement of patients in each intervention group is based on a randomized blocking method. For each treatment method, we created 6 blocks, and then we created random numbers through the computer, and then we sorted the blocks on them, and then we randomly assign each of them to each group. It is an individual randomization unit. Hiding is also done by using encrypted envelopes. The drugs are encrypted in envelopes and given by the nurse, and the information is collected by the poisoning fellowship.

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients over 18 years of age with acute intoxication admitted to the ICU and without dementia. Exclusion criteria: 1. Those who take antipsychotic drugs for any reason Patients are using alcohol or benzodiazepine 3. Patients who were allergic to haloperidol or olanzapine, 4. The patient has severe agitation.

Intervention groups

Patients with delirium, one group receiving olanzapine 5 mg 3 times a day, and the other group receiving haloperidol 3 mg 3 times a day for up to 5 days, depending on the response to treatment.

Main outcome variables

The outcome of the study is a change in the symptom of delirium on the basis of the MDAS score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190928044909N1**

Registration date: **2020-07-21, 1399/04/31**

Registration timing: **retrospective**

Last update: **2020-07-21, 1399/04/31**

Update count: **0**

Registration date

2020-07-21, 1399/04/31

Registrant information

Name

Javad Mesbahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5102 5000

Email address

j.mesbahi1969@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of haloperidol and olanzapine in the treatment of delirium patient admitted in ICU

Public title
Effect of olanzapine in delirium of poisoning patient

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria included patients over 18 years of age who had acute intoxication without dementia
Exclusion criteria:
Patients who take antipsychotic drugs for any reason
Patients are using alcohol or benzodiazepine
Patients who were allergic to haloperidol or olanzapine, Patients who have severe agitation

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
We randomly generated 6 blocks for the study intervention and then generated random numbers from the computer and then arranged the blocks on them and then randomly assigned each group to each individual randomization unit. . Hiding is also done by using randomly formatted encrypted boxes.

Blinding (investigator's opinion)
Double blinded

Blinding description
The medication is given to the nurse in anonymous envelopes by the nurse and noted in the questionnaire form. The patient does not know the type of medication

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Committee on Ethics in Biomedical Research
Street address

Loghman Hospital, Makhsos Ave
City
Tehran
Province
Tehran
Postal code
1333631151
Approval date
2019-11-25, 1398/09/04
Ethics committee reference number
ir.sbmuretech.rec.1398.426

Health conditions studied

1

Description of health condition studied

delirium patient admitted in ICU

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changes in the symptoms of delirium: All symptoms related to decreased attention and memory impairment are eliminated. Response to treatment is based on changes in MDAS scores. Impairment is resolved. The response to treatment is based on improvement in the MDAS score.

Timepoint

Treatment results are evaluated by the researcher on days 3 and 5.

Method of measurement

Delirio intensity is measured on the MDAS score, which includes 10 items and 4 points. This intensity will be rated in MDAS ≤ 15 as "mild", in $16 \leq \text{MDAS} \leq 22$ as "moderate" and in $23 \leq \text{MDAS} \leq 30$, it will be rated "severe". The remission index for this disease based on this score is MDAS values less than 10

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: olanzapine pill 5 mg, made by Marham Daroo Company and is prescribed orally every 8 hours to three days

Category

Treatment - Drugs

2

Description

Control group: Halopiridolis pill 5 mg, made by Iran

Daroo Company and is prescribed orally every 8 hours to three days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

ICU Poisoning in Loghman Hospital

Full name of responsible person

Javad Mesbahi

Street address

Loghman Hospital ,Makhsos Avenue

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Web page address

<http://www.sbm.ac.ir/SiteDirectory/Loghmanhospi>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Rahimi

Street address

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Email

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Web page address

<https://Rasekhoon.Net>

Grant name

Research

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Poisoning Research Center

Proportion provided by this source

20

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Javad Mesbahi

Position

Flowship

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

The protocols will be posted on the Poisoning Center website

When the data will become available and for how long

Access started in 1399

To whom data/document is available

Researchers Working in Academic and Scientific Institutions

Under which criteria data/document could be used

Used only in scientific medical research

From where data/document is obtainable

With permission from the Director of Loghman Hospital Poisoning Research Center

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

Written request from Loghman Poisoning Center

Comments