Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the efficacy of haloperidol combination with midazolam versus haloperidol ketamine in patients with agitation in emergency room

Protocol summary

Study aim

Comparison of the efficacy of haloperidol combination with midazolam versus haloperidol ketamine in patients with agitation in emergency room

Design

This double blind randomized clinical trial conducted on agitated patients admitted in Emergency ward of Shariati Hospital. Sample size is 70 and each group consist of 35 patients and randomly assigned to each group by a computerized software in according to arrival time. Control group receive iv midazolam 0.05 mg/kg and iv haloperidol 2.5 mg/kg. Intervention group receive 0.5 mg/kg iv ketamine and 2.5 mg iv haloperidol. Then level of tranquilizing, possible complication, RR, BP and Spo2 assessed by AMSS in interval time 0, 5, 15, 30, 69, 90, 120 min and 4 hours after intervention.

Settings and conduct

This study conducted in emergency department of Shariati Hospital in patient who have inclusion criteria of the study during of the study. Person who compete the checklist and analyzer are blind to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All agitated patients > 18 y/o who admitted to emergency ward. Exclusion criteria: Pregnant patients, age < 18 y/o, sever head trauma and suspected ICP rising, history of seizure, shock and unstable vital sign, unwilling to participate in the study, hypoglycemia, hypoxemia, and any other treatable medical condition.

Intervention groups

Group A: will receive 2.5 mg haloperidol and 0.05 mg/kg midazolam Group B: will receive 0.5 mg/kg ketamine and 0.05 mg/kg midazolam

Main outcome variables

The main outcome is level of rationalization by Altered mental state score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120130008872N13**
Registration date: **2019-10-23, 1398/08/01**
Registration timing: **prospective**

Last update: **2019-10-23, 1398/08/01**
Update count: **0**

Registration date

2019-10-23, 1398/08/01

Registrant information

Name

Morteza Saeedi

Name of organization / entity

Country

Iran (Islamic Republic of)

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m_saeedi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-20, 1398/08/29

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the efficacy of haloperidol combination with midazolam versus haloperidol ketamine in patients with agitation in emergency room

Public title
Haloperidol midazolam versus ketamine midazolam in agitated patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All agitated patients above 18 years old and admitted to emergency ward
Exclusion criteria:
Pregnant women age<18 y sever head trauma suspected ICP rising seizure history unwilling to participation in the study hypoglycemia hypoxemia all conditions that have treatable medical condition as a reason for agitation
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
patient in order of arrival with a randomization software allocated individually in to separate groups. sample size is 70 and the range of numbers are 1 to 70 and each number belong only to one patient and do not repeat. one group receive midazolam and haloperidol and the other on will receive haloperidol and ketamine.
Blinding (investigator's opinion)
Double blinded
Blinding description
Researcher allocated the patient to each group(A or B) in according the arrival time and specific number and then the nurse deliver drugs to the patient. Patients are blinded to type of drugs. Checklist fill by a person who is blinded to type of delivered drug. Data analyzer is also blinded to the type of drug because he or she is blinded to the type to drugs that delivered to group A and B.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences, School of Medicine
Street address
Poursina Street, 16 Azar Street, Bolvar Keshavarz Ave.
City
Tehran
Province
Tehran
Postal code
1411713135
Approval date
2018-11-10, 1397/08/19
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.532

Health conditions studied

1

Description of health condition studied
agitation
ICD-10 code
agitation
ICD-10 code description

Primary outcomes

1

Description
Agitation level
Timepoint
Before intervention and 5, 15, 30, 90, 120 min and 4 hours after intervention
Method of measurement
altered mental scale score(AMSS)

Secondary outcomes

1

Description
spo2
Timepoint
Before intervention and 5, 15, 30, 90, 120 min and 4 hours after intervention
Method of measurement
pulsoxymerer

2

Description
Respiratory Rate
Timepoint

Before intervention and 5, 15, 30, 90, 120 min and 4 hours after intervention

Method of measurement

numbers per min

3

Description

Blood pressure

Timepoint

Before intervention and 5, 15, 30, 90, 120 min and 4 hours after intervention

Method of measurement

mmhg

Intervention groups

1

Description

Intervention group: A Before intervention and 5, 15, 30, 90, 120 min and 4 hours after intervention haloperidol

Category

Treatment - Drugs

2

Description

Control group: B will receive 2.5 mg haloperidol iv and 0.5 mg/kg iv ketamine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Morteza Saeedi

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North Amirabad Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh Basti

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Building No 1, North entrance door of Tehran University, Poursina sreet, Qods street, Enghelab 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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Morteza Saeedi

Position

Associate professor/ Emergency Medicine specialist

Latest degree

Specialist

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

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Associate professor/ Emergency Medicine specialist

Latest degree
Specialist

Other areas of specialty/work
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Position
Emergency Medicine Specialist; Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Emergency Medicine

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Web page address

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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The raw data and coded information of the patients participating in the study can be provided

When the data will become available and for how long
In the end of the study and after publication of the results the data will be available and we have plan to preserve data for 10 years

To whom data/document is available
Person with academic position

Under which criteria data/document could be used
In order to conduct and design future study in this field

From where data/document is obtainable
email contact with Mr. Morteza Saeedi; m_saeedi@tums.ac.ir

What processes are involved for a request to access data/document
After confirmation of applicant identity, we will contact him/her by email

Comments