

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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, 60, 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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+98 21 8490 2719

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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 severe head trauma suspected ICP rising seizure history unwilling to participate 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

pulsoxymeter

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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Position

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Latest degree

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Latest degree

Specialist

Other areas of specialty/work

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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