Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of sedation effect of midazolam and muscle haloperidol in treatment of agitation of patients

Protocol summary

Study aim

Considering that studies performed in the treatment of agitation have been performed on patients after surgery and the cause of agitation in these patients can be as a side effect of anesthesia; However, agitation in the emergency department is due to other factors such as psychological causes, alcohol poisoning, etc., and studies in this field are limited. Also considering that the use of benzodiazepines may cause complications such as delirium in patients; Therefore, the aim of this study was to compare the sedative effect of midazolam and haloperidol muscle on the treatment of agitation and its complications in patients referred to the emergency department of Khatam Al-Anbia Hospital in Zahedan in 2019-2020.

Design

Assignment to each of the two groups will be randomly assigned blocking with ten blocks. A total of 56 people in each group and a total of 112 were estimated that 60 people from each group will enter for more assurance and if conditions are available and for higher accuracy.

Settings and conduct

Samples will be made based on the admission conditions of patients available from patients referred to the emergency room of Khatam Al-Anbia Hospital (PBUH) in Zahedan.

Participants/Inclusion and exclusion criteria

Includes age 15 to 60 years, class π and ASA I, with a score above 28 on the agitation measurement scale.

Intervention groups

After obtaining the consent of the patient and having the desired criteria, the drugs are injected intramuscularly into the patient's left deltoid muscle with a 2 cc syringe. After injecting the drug, the patient is monitored for two hours. After 30, 60 and 15 minutes, they are measured for drug response (agitation control) and at the end of two hours for side effects.

Main outcome variables

Acute agitation, emergency department, haloperidol, midazolam, sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200720048146N1**
Registration date: **2020-10-04, 1399/07/13**
Registration timing: **prospective**

Last update: **2020-10-04, 1399/07/13**
Update count: **0**

Registration date

2020-10-04, 1399/07/13

Registrant information

Name

Mohamadhosen Ajdary

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3223 6976

Email address

mohamadhosenajdary1347zabol@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of sedation effect of midazolam and muscle haloperidol in treatment of agitation of patients

Public title
Comparison of sedation effect of midazolam and muscle haloperidol in treatment of agitation of patients referring to emergency

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Includes age 15 to 60 years Class п ASA I Score above 28 on the agitation measurement scale

Exclusion criteria:
Patient dissatisfaction (or legal partner) Unstable vital signs (blood pressure less than 90 mm Hg, heart rate below 60 and above 120 beats per minute, oxygen saturation level below 90%, level of consciousness less than agitation) History of heart disease and liver and kidney failure Pregnancy and lactation The patient is very restless and has the potential to harm himself and others and can not wait for a response to intramuscular injection of the drug. Poisoning with an unknown drug A history of active seizures requires medication Myasthenia Gravis Bone marrow suppression Patients with coagulation disorders such as hemophilia in whom intramuscular injection is contraindicated Thyrotoxicosis Hypersensitivity to midazolam or haloperidol

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
1

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
نمونه ها بر اساس شرایط ورود بیماران بصورت در دسترس از مراجعین به اورژانس بیمارستان خاتم الانبیاء (ص) زاهدان صورت خواهد گرفت و اختصاص به هر یک از دو گروه بصورت اختصاص تصادفی بلوک بندی شده با بلوک های ده تایی خواهد بود

Blinding (investigator's opinion)
Double blinded

Blinding description
After selecting patients for inclusion and exclusion criteria, drugs including midazolam 5mg or haloperidol 5mg are prepared by block randomization method. They are coded by the person in charge of the research, so that the doctor and the patient do not know the type of injectable drug.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
National Ethics System in Biomedical Research

Street address
Khatam Hospital Emergency

City
Zahedan

Province
Sistan-va-Balouchestan

Postal code
981777674

Approval date
2020-01-05, 1398/10/15

Ethics committee reference number
IR.ZAUMS.REC.1399.070

Health conditions studied

1

Description of health condition studied
Agitation

ICD-10 code
R45.1

ICD-10 code description
Restlessness and agitation

Primary outcomes

1

Description
Agitation

Timepoint
The patient is monitored for two hours after the injection. After 30, 60 and 15 minutes, they are measured for drug response (agitation control) and at the end of two hours for side effects.

Method of measurement
Drug response rate is defined according to the agitation measurement scale (score less than 28).

2

Description
Midazolam and haloperidol

Timepoint
At the beginning of the intervention

Method of measurement
Medications containing midazolam 5mg, or haloperidol 5mg, are prepared by block randomization. They are

coded by the person in charge of the research, so that the doctor and the patient do not know the type of injectable drug. After obtaining the consent of the patient and having the desired criteria, the drugs are injected intramuscularly into the patient's left deltoid muscle with a 2 cc syringe.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Haloperidol 5mg is prepared by block randomization method. It is coded by the researcher, so that the doctor and the patient do not know the type of injectable drug. After obtaining the consent of the patient and having the desired criteria, the drugs are injected intramuscularly into the patient's left deltoid muscle with a 2 cc syringe. The patient is monitored for two hours after the injection. After 30, 60 and 15 minutes, it is measured in terms of drug response (agitation control) and at the end of two hours, in terms of side effects. Drug response rate is defined according to the agitation measurement scale (score less than 28).

Category

Treatment - Drugs

2

Description

Control group: Midazolam 5mg is prepared by block randomization method. It is coded by the researcher, so that the doctor and the patient do not know the type of injectable drug. After obtaining the consent of the patient and having the desired criteria, the drugs are injected intramuscularly into the patient's left deltoid muscle with a 2 cc syringe. The patient is monitored for two hours after the injection. After 30, 60 and 15 minutes, it is measured in terms of drug response (agitation control) and at the end of two hours, in terms of side effects. Drug response rate is defined according to the agitation measurement scale (score less than 28).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam Al-Anbia Hospital Emergency Room (PBUH)

Full name of responsible person
Mohammad hossein Ajdari

Street address
Khatam Hospital Emergency

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zahedan University of Medical Sciences

Full name of responsible person
mohammad hossein Ajdari

Street address
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
mohammad hossein Ajdari

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no more information.

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available