Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison between the efficay of tranquillisation and side effects of midazolam, haloperidol and the combination of these two drugs on agitated patients in emergency rooms

Protocol summary

Summary

ER department is confronting significant number of agitated patients daily, for this reason this study is presenting the comparison between the efficay of tranquillisation and side effects of midazolam, haloperidol and the combination of these two drugs on agitated patients in emeregency rooms.This is a double blind clinical trial. Inclusion criteria:18 to 80 years old agitated patients with agitated behavior scale score of more than 28.Exclusion criteria : Disagreement of patient's relatives on participation in the survey; Unstable vital signs; Past medical history of cardiac disease ,renal and liver failure; Pregnancy; Lacation; Poisoning with unknown drugs; Past medical history of seizure; Allergy to midazolam and haloperidol. In this study 126 samples (patients) need to be selected from Esfand 94 till Alban 95. Drugs(Midazolam 1cc, Haloperidol 1cc, Combination of midazolam and haloperidol 1cc) need to be prepared by block randomization method and they will be coded by research 's attendant. At this point the patient and physician have no idea about the type of injected drug. After getting patient's relatives ' authorization and meeting the expected criteria , drug will be injected intramusculary with 2cc syringe. Patient will be observed for at least two hours , the response to drug will be checked in an hour and also drug 's side effects will be recorded after two hours. The favorable result will be the patient 's agitated behavior scale score of less than 28. Finally the correlation between sex and age with the efficacy of the drugs, delerium with the efficacy of dugs , evaluation of drug's side effects and their correlation with type of the drugs that are being used and the correlation between the interference of the physician with type of the drug will be evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301199162N8**
Registration date: **2016-03-30, 1395/01/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-03-30, 1395/01/11

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences

Expected recruitment start date

2016-03-15, 1394/12/25

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison between the efficay of tranquillisation and side effects of midazolam, haloperidol and the combination of these two drugs on agitated patients in emergency rooms

Public title
Comparison of the effects and side effects of midazolam, haloperidol and the combination of them in agitated patients

Purpose
Supportive

Inclusion/Exclusion criteria
Exclusion criteria:Unstable vital signs(systolic blood pressure less than 90mmHg ,pulse rate less than 60 or more than 120/min and level of consciousness lower than agitation);past medical history of seizure;patients with unknown drug poisoning;Severe agitated patients who can not wait for the effect of intramuscular form of drugs;Allergy to midazolam and haloperidol; Closed angle glaucoma; Parkinson disease;Pregnancy and lactation; Myasthenia gravis;Thyrotoxicosis; Bone marrow suppression; Disagreement of patient's relatives on participation in the survey;Patients with coagulotion disorders such as hemophilia whom intramuscular injection is contraindicated; Reversible causes of agitation such as hypoglycemia (blood sugar less than 50),pain due to MI;Prolonged QT in patients ECG (QT >0.44) Inclusion criteria: 18 to 80 years old gitated patients with agitated behavior scale score of more than 28 .

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

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

Street address
tehran,bulvare keshavarz ,16azar avenue ,tehran unkversity of medical sciences,

City
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Postal code

Approval date
2015-08-23, 1394/06/01

Ethics committee reference number
IR.TUMS.REC.1394.631

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
tranquilization(control of agitation)

Timepoint
one hour after drug injection

Method of measurement
by physician with agitated behaviour scale

Secondary outcomes

1

Description
side effects include:seizure ,extrapyramidal reactions:dystonia,akathisia,tardive dyskinesia,dizziness,neuroleptic malignant syndrom,nausea and vomiting,apnea or respiratory depression,pain in site of injection,cardiorespiratory arest

Timepoint
30,60,120 min after drug injection

Method of measurement
physician 's examination and also checking vital signs

Intervention groups

1

Description
In this study drugs which are going to be prepared by the

method of Block Randomization would be injected to patients with agitated behavior scale score of more than 28. Midazolam(5 miligram=1cc), haloperidol(5miligram=1cc) and the combination of midazolam (2.5 miligram) and haloperidol(2.5 miligram) with 2cc syringe will be injected intramusculry. In the next step, the patient's vital signs need to be documented and then drug will be injected.Patients will be under observed for 2 hours. Finally the response to the drug will be checked in an hour and also drug's side effects will be recorded after 2 hours.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Emergency Room
Full name of responsible person
Atousa Akhgar
Street address
Keshavarz Boulevard , Tehran
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty