

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison between the efficacy 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 efficacy of tranquillisation and side effects of midazolam, haloperidol and the combination of these two drugs on agitated patients in emergency 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; Location; 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 intramuscularly 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, delirium with the efficacy of drugs, 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

Amir Nejati

Name of organization / entity

Tehran University of Medical Sciences, Imam Khomeini Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2240

Email address

a-nejati@tums.ac.ir

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 efficacy 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 coagulation 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
unkiversity of medical sciences,

City

tehran

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

City

Tehran

2**Recruitment center****Name of recruitment center**

Sina Hospital Emergency Room

Full name of responsible person

Atousa Akhgar

Street address

Hasan Abad St. , Tehran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University Of Medical Sciences

Full name of responsible person

Amir Nejati

Street address

Imam Khomeini Hospital , Keshavarz Boulevard

City

Tehran

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**Contact****Name of organization / entity**

Tehran University Of Medical Sciences

Full name of responsible person

Atousa Akhgar

Position

Emergency Medicine Resident

Other areas of specialty/work**Street address**

Poursina St. , Qods St. , Enghelab Avenue

City

Tehran

Postal code**Phone**

+98 21 6640 4377

Fax**Email**

At.akhgar@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University Of Medical Sciences

Full name of responsible person

Amir Nejati

Position

Professor

Other areas of specialty/work**Street address**

Poursina St. , Qods St. , Enghelab Avenue

City

Tehran

Postal code**Phone**

+98 21 6640 4377

Fax**Email**

Anejati@tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University Of Medical Sciences

Full name of responsible person

Atousa Akhgar

Position

Emergency Medicine Resident

Other areas of specialty/work**Street address**

Poursina St , Qods St , Enghelab Avenue

City

Tehran

Postal code**Phone**

+98 21 6640 4377

Fax**Email**

At.akhgar@gmail.com

Web page address**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