Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of the effect of midazolam drug with placebo in improving the symptoms of hysterical patients referred to the emergency department

Protocol summary

Study aim
The effect of midazolam on reducing the symptoms of hysteria

Design
The clinical trial has a control group with parallel, three-blind, randomized, phase 3 groups on 80 patients. For randomization, variable block is used. For three-way blinding and hiding the sequence of drugs, they are placed in an envelope with a code and given to the first group, midazolam and placebo (distilled water) to the secound group. Before and after 30 and 60 minutes of the intervention, the variables evaluated.

Settings and conduct
Patients with hysterical symptoms (restlessness, crying and lack of communication, dysphonia or aphonia) are included in the study after checking the input and output criteria with the Emergency medicine specialist on duty. After randomization, for the group The first ampoule of midazolam of Elixir pharmaceutical company is infused in the amount of 2 cc and the second group of distilled water in the amount of 2 cc is intravenously infused for 2 minutes. In order to blind the patients and the evaluator of the results, drug and placebo are placed in similar syringes in envelopes with numerical codes. For analysis, the information of the drug and placebo groups is given to the data analyst in the form of groups A and B.

Participants/Inclusion and exclusion criteria
Inclusion criteria: All patients with hysteria referred to the emergency room, informed consent of the patient or his companion Exclusion criteria: age less than 18 years and more than 60 years old - pregnancy - history of liver disease - allergy to the study drugs

Intervention groups
Intervention group: midazolam ampoule for patients in the amount of 2 mg, which has reached the volume of 2 CCs with distilled water, intravenously within 2 minutes. Control group: intravenous distilled water 2 CCs in 2 minutes.

Main outcome variables
The presence of symptoms of hysterical patients, drug side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054869N4**
Registration date: **2023-01-19, 1401/10/29**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-19, 1401/10/29**
Update count: **0**

Registration date
2023-01-19, 1401/10/29

Registrant information

Name
ali abdolrazaghnejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of midazolam drug with placebo in improving the symptoms of hysterical patients referred to the emergency department

Public title

The effect of midazolam on the improvement of hysteria symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All confirmed hysterical patients by emergency medicine specialists in the emergency room Informed consent of the patient or her / his companion

Exclusion criteria:

Age less than 18 years and more than 60 years pregnacy History of liver disease Allergy to study drugs

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization sequence based on variable block size will be obtained from the "Random allocation". To hide the random allocation, coded envelopes are used based on the created random sequence. Inside the envelopes are drugs and placebos based on a random sequence. The envelopes have the same shape, same weight, one They are color. The only codes on the envelopes will indicate the contents of the medicine or placebo.

Blinding (investigator's opinion)

Triple blinded

Blinding description

For triple blinding, drug and placebo are in pre-prepared single-shaped syringes in numbered envelopes. After opening the envelope and assigning the syringe to the patients, the envelope code is written in the patient evaluation form. The patient, the outcome assessor and the data analyst do not know about the contents and codes of the envelopes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Islamic Azad University-Zahedan Branch

Street address

Zahedan ,Islamic Azad University, University Street,

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743545

Approval date

2022-10-15, 1401/07/23

Ethics committee reference number

IR.IAU.ZAH.REC.1401.055

Health conditions studied

1

Description of health condition studied

Hysterical patients

ICD-10 code

F44

ICD-10 code description

Dissociative and conversion disorders

Primary outcomes

1

Description

Agitation

Timepoint

0, 30, 60 minutes

Method of measurement

The presence or absence of symptoms based on clinical diagnosis by an emergency physician

2

Description

Failure to communicate with others

Timepoint

0, 30, 60 minutes

Method of measurement

The presence or absence of symptoms based on clinical diagnosis by an emergency physician

3

Description
to cry
Timepoint
0, 30, 60 minutes
Method of measurement
The presence or absence of symptoms based on clinical diagnosis by an emergency physician

4

Description
dysphonia
Timepoint
0, 30, 60 minutes
Method of measurement
The presence or absence of symptoms based on clinical diagnosis by an emergency physician

Secondary outcomes

1

Description
weaknes
Timepoint
60 minutes after the intervention
Method of measurement
According to the history of the patient

2

Description
Drowsiness
Timepoint
0, 30, 60 minutes
Method of measurement
The presence or absence of symptoms based on clinical diagnosis by an emergency physician

3

Description
Apnea
Timepoint
30,6o minutes
Method of measurement
The presence or absence of symptoms based on clinical diagnosis by an emergency physician

4

Description
Decreased breathing rate
Timepoint
0,30,60 minutes
Method of measurement
The presence of a normal breathing rate of less than 12 per minute by observing the movements of the chest by an emergency physician

Intervention groups

1

Description
Intervention group: EXIR pharmaceutical company's midazolam ampoule is 2 mg in a volume of 2 cc, which will be infused intravenously for 2 minutes.
Category
Treatment - Drugs

2

Description
Control group: 2 cc of distilled water will be infused intravenously for 2 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Khatam-Al-Anbia hospital
Full name of responsible person
Ali Abdolrazaghnejad
Street address
Khatam square
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9815733169
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ali.abdorazzagh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Normohammad Bakhshani
Street address
Daneshgah Blvd
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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
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
Ali Abdolrazaghnejad
Position
Associate professor
Latest degree
Specialist
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data of this research can be shared after de-identification.
When the data will become available and for how long
Access will start one year after the results are published.
To whom data/document is available
Only researchers working in academic and scientific institutions will be allowed to access the data.
Under which criteria data/document could be used

Any statistical analysis will be possible for academic researchers to find out the relationship between the variables

From where data/document is obtainable

Requests should be sent in writing to the responsible author's email.

What processes are involved for a request to access data/document

The claimant sends her /his written request and a valid ID card and employment certificate in a scientific or university institution to the responsible author via email and after the necessary checks, she /he will receive a response to her request within 2 weeks.

Comments