Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effect of diazepam alone and in combination with haloperidol in controlling agitation caused by stimulants

Protocol summary

Study aim
Comparison of the effect of diazepam alone and in combination with haloperidol in controlling agitation caused by stimulants

Design
The method of randomization is the use of black and white beads. In this method, the black bead will be the intervention group and the white bead will be the control group. blind on both sides

Settings and conduct
The research population is those patients referred to the emergency department of hospitals affiliated to Shahid Beheshti University of Medical Sciences, who referred to this center in 1401 for the treatment of agitation caused by stimulants, according to this, all these patients were not randomized. Asan is considered as a study group in the intervention and control group. After the desired patients (N=60) were selected, the randomization method is using black and white beads. In this method, the black bead will be the intervention group and the white bead will be the control group. In the continuation of the treatment of the patients, in the diazepam group, this drug will be used with a dose of 10 mg, and in the diazepam (10 mg) + haloperidol (5 mg) group, this drug will be used. In order to evaluate the state of restlessness and relaxation, the Richmond 3 index will be used.

Participants/Inclusion and exclusion criteria
Entry criteria: over 18 years old. Exclusion criteria: lack of consent to participate in the study, presence of risk factors for cognitive disorders such as brain and nerve disease, history of moderate to severe head trauma, history of head trauma, decreased level of consciousness, glaucoma, psychosis, moderate to severe substance dependence Other, heart diseases such as long QT 2 and observing side effects of used drugs

Intervention groups
Diazepam group, from this drug with a dose of 10 mg and diazepam group (10 mg) + haloperidol (5 mg)

Main outcome variables
agitation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210720051946N6**
Registration date: **2024-01-07, 1402/10/17**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-07, 1402/10/17**
Update count: **0**

Registration date
2024-01-07, 1402/10/17

Registrant information

Name
Peyman Erfan Talab Evini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5102 5000

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peyman1346erfan@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-14, 1402/09/23

Expected recruitment end date
2024-03-19, 1402/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of diazepam alone and in combination with haloperidol in controlling agitation caused by stimulants

Public title
Effect of diazepam and haloperidol in controlling agitation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria include consent to participate in the study, diagnosis of agitation with DSM 5 1 criteria following the consumption of stimulants and age over 18 years.

Exclusion criteria:
On the other hand, another set of indicators is considered as exclusion criteria, these exclusion criteria include lack of consent to participate in the study, the presence of risk factors for cognitive disorders such as the presence of brain and nerve diseases (such as seizures, dementia, Parkinson's).), a history of moderate to severe head trauma, a history of head trauma, decreased level of consciousness, glaucoma, psychosis, moderate to severe dependence on other substances, heart diseases such as long QT 2, and observation of the side effects of the drugs used.

Age
From **18 years** old

Gender
Both

Phase
0

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
After the desired patients (N=60) were selected, the patients were randomly and double-blindly divided into intervention and control groups. The randomization method was the use of black and white beads. In this method, the black bead will be the intervention group and the white bead will be the control group. Also, in order to blind the patients, they will be blinded to the other group. In the continuation of the treatment of the patients, in the diazepam group, this drug will be used with a dose of 10 mg, and in the diazepam (10 mg) + haloperidol (5 mg) group, this drug will be used. In the following, to evaluate the level of agitation, the evaluation of the level of sedation is used and its level is determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
After the desired patients (N=60) were selected, the patients were randomly and double-blindly divided into intervention and control groups. The randomization method was the use of black and white beads. In this method, the black bead will be the intervention group and the white bead will be the control group. Also, in order to blind the patients, they will be blinded to the other group. In the continuation of the treatment of the patients, in the diazepam group, this drug will be used with a dose of 10 mg, and in the diazepam (10 mg) + haloperidol (5 mg) group, this drug will be used. In the following, to evaluate the level of agitation, the evaluation of the level of sedation is used and its level is determined.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of Shahid Beheshti University of Medical Sciences

Street address
Velenjak Square, Daneshju Blv

City
Tehran

Province
Tehran

Postal code
1983969411

Approval date
2023-11-19, 1402/08/28

Ethics committee reference number
IR.SBMU.RETECH.REC.1402.451

Health conditions studied

1

Description of health condition studied
poisoned patients

ICD-10 code
F00-F99

ICD-10 code description
F00-F99

Primary outcomes

1

Description

agitation

Timepoint

0,10,15,30 min

Method of measurement

richmond questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Diazepam (10 mg) + Haloperidol (5 mg)

Category

Treatment - Drugs

2

Description

Control group: Diazepam (10 mg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hospital

Full name of responsible person

Peyman Erfan Talab Evini

Street address

Kamali Street

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Postal code

1333631151

Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Peyman Erfan Talab Evini

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Province

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Peyman Erfan Talab Evini

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Toxicology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work
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Person responsible for updating data

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Shahid Beheshti University of Medical Sciences

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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 is potentially shareable after de-identifying individuals

When the data will become available and for how long
The access period starts from the year 2024

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
People who are also engaged in pharmaceuticals and research

From where data/document is obtainable
Peyman Erfan Talab Evini

What processes are involved for a request to access data/document
Administrative correspondence seven to ten working days

Comments