Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Comparison of the effectiveness of intramuscular olanzapine with intramuscular haloperidol for the treatment of agitation in patients with Bipolar Disorder, A randomized controlled study.

Protocol summary

Study aim
Comparison of the effect of intramuscular Olanzapine and Haloperidol in the treatment of agitation in patients with Bipolar Disorder.

Design
Clinical trial, parallel groups, double blind, semi-randomized controlled, phase 4 on 40 patients

Settings and conduct
patients are transferred to one of the two women wards of the Razi hospital in Tehran based on the capacity of the wards and in turn, to control the agitation, in one of the two wards, the Olanzapine and in the other ward the Haloperidol were provided to the staff

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having an overall score of 14 and above in PANSS and having a score of 4 (max 7) in at least one of its five cases. No physical illness associated with mental retardation or other cognitive and neurological disorders and patients with a history of NMS. No dependence or abuse of substances, drugs or alcohol Exclusion criteria: Patients with a history of allergic reaction or intolerance to Olanzapine or Haloperidol. Patients with psychomotor restlessness who have not been diagnosed with Bipolar Disorder. Pregnant or nursing women. Patients who have received antipsychotics depo-injectable drugs during the last 1 month. Patients who have used psychological stimuli within 1 week. Patients who received benzodiazepines within the last 4 hours. Patients who have received oral or rapid muscular antipsychotics in the last 2 hours

Intervention groups
Samples will be selected from patients between 18 and 65 years old admitted to the psychiatric ward of Razi Hospital in 1401 who have a diagnosis of bipolar disorder. Patients are transferred to one of the two wards of the women's hospital. In order to control the agitation, in one of the two wards, Olanzapine and in the other part of the injectable Haloperidol were provided to the staff

Main outcome variables
PANSS ؛ RASS ؛ MSAS

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230131057294N1**
Registration date: **2024-02-25, 1402/12/06**
Registration timing: **prospective**

Last update: **2024-02-25, 1402/12/06**
Update count: **0**

Registration date
2024-02-25, 1402/12/06

Registrant information

Name
Marzieh Khodaparast

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4445 2713

Email address
marzieh.kh1994@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-04-08, 1403/01/20

Expected recruitment end date
2024-06-09, 1403/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of intramuscular olanzapine with intramuscular haloperidol for the treatment of agitation in patients with Bipolar Disorder, A randomized controlled study.

Public title
Comparison of the effectiveness of intramuscular olanzapine with intramuscular haloperidol for the treatment of agitation in patients with Bipolar Disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Bipolar Disorder diagnosed based on DSM-5 criteria according to clinical interview of psychiatrist. Having an overall score of 14 and above (up to 35) in PANSS including five cases of tension, uncooperativeness, hostility, poor impulse control and excitement. Having a rating of 4 (max 7) in at least one of the above five The psychiatrist concludes that the patient should be treated with Olanzapine IM injection or Haloperidol No physical illness associated with mental retardation or other cognitive disorders and neurological disorders Not having severe cardiovascular diseases or cerberovascular in the past 6 months, any severe, acute or unstable medical conditions or laboratory disorders and uncontrolled underlying disease No NMS history No dependence or abuse of substances, drugs or alcohol acutely or in the past 12 months except nicotine or positive urine screen test Patient or guardian's consent
Exclusion criteria:
Patients with a history of allergic reaction or intolerance to Olanzapine or Haloperidol. Patients with psychomotor restlessness who have not been diagnosed with bipolar disorder. Unwillingness of the patient or the patient's family to participate in the study. Pregnant or nursing women Patients who have received antipsychotics depo-injectable drugs during the last 1 month. Patients who have used psychological stimuli within 1 week. Patients who received oral or injectable benzodiazepines within the last 4 hours. Patients who have received oral or rapid muscular antipsychotics in the last 2 hours.
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
4
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In psychiatric patients (women) on arrival to Razi Psychiatric Hospital, according to the capacity of wards and in turn, by admission and emergency staff, are transferred to one of the two wards of the hospital. (In the reception system of patients in the emergency room of Razi psychiatric hospital, patients who need to be admitted to one of the two wards of the hospital according to the psychiatrist's diagnosis, are referred to one of the two wards of gynecology by the reception officer) in each of those wards, one of two drugs A or B (haloperidol or olanzapine) is used to control the agitation of patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
For double-blind research, a label is attached to the injected drugs in each part so that the name of the drugs is not seen. One part A and the other is written on the drug B. Neither the patient nor the researcher is aware of the type of drug A or B. In medical instructions, a or B drug injection is written for each section. At the end of the study, the researcher is informed of the type of drug A and B.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of The University of Rehabilitation Sciences and Social Health
Street address
At the end of 6th St.,Velenjak,Tehran
City
tehran
Province
Tehran
Postal code
1985713871
Approval date
2024-01-24, 1402/11/04
Ethics committee reference number
IR.USWR.REC.1402.244

Health conditions studied

1

Description of health condition studied
Bipolar disorder
ICD-10 code

F31

ICD-10 code description

Bipolar disorder

Primary outcomes

1

Description

Positive and Negative Symptom Scale score

Timepoint

15 minutes, 1 hour and 24 hours later

Method of measurement

Positive and Negative Symptom Scale

2

Description

Modified Simpson-angus scale score

Timepoint

15 minutes, 1 hour and 24 hours later

Method of measurement

Modified Simpson-angus scale

3

Description

Richmond Agitation-Sedation Scale score

Timepoint

15 minutes, 1 hour and 24 hours later

Method of measurement

Richmond Agitation-Sedation Scale

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Intramuscular injection of (A or B) Olanzapine 10 mg, maximum 3 doses in 24 hours, second injection after at least 2 hours from the first injection and third injection after at least 4 hours of second injection at discretion, to control the agitation.

Category

Treatment - Drugs

2

Description

Second intervention group: Intramuscular injection of (A or B) Haloperidol 5 or 10 mg, maximum 3 doses in 24 hours, second injection after at least 2 hours from the first injection and third injection after at least 4 hours of second injection at discretion, to control the agitation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Psychiatric Hospital

Full name of responsible person

Marzieh Khodaparast

Street address

Razi Psychiatric Hospital, Amin Abad, Shahid Rastegar Blvd, Taghi Abad Street, Shahre-rey

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamidreza Khankeh

Street address

At the end of 6th St., Velenjak, Tehran

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1985713871

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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

University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Marzieh Khodaparast

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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No. 8, Unit 14, first Mahestan, Besat Blvd, Jannat Abad markazi

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Person responsible for scientific inquiries

Contact

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Marzieh Khodaparast

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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