Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Oct 2026

The Comparison of Sedation Induction Time of Haloperidol, Perphenazine, Chlorpromazine, Promethazine, Trifluoperazine on Aggressive Patients

Protocol summary

Study aim
To compare the drugs that routinely used as sedative drugs in the emergencies. According to how rapid they act and complication of the first hour of injection in the patient which is observed.

Design
4 parallel groups randomised trial with unblinded and outcome assessment

Settings and conduct
This study was on aggressive patients who referred to psychiatry emergency department. 76 patients were randomly divided into 4 groups and received Haloperidol, Promethazine, Chlorpromazine and Trifluoperazine intramuscularly.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age>18 years; Have consent to enter the study by patient accompaniment; Have no Contraindication for interventional Drugs (For instance muscle rigidity and Neuroleptic Malignant Syndrome); Having verbal violence in the time of the first visit; Having physical violence in the time of the first visit Exclusion criteria: Patient Family's refuse for Collaboration After the First Agreement.

Intervention groups
Intervention group 1: Haloperidol injection, Intervention group 2: Promethazine injection, Intervention group 3: Chlorpromazine injection, Intervention group 4: Trifluoperazine injection We injected Haloperidol 5mg in the first group, 50 mg Promethazine in the second group, 50 mg Chlorpromazine in the third one and Trifluoperazine 1 mg in the fourth one, Intramuscularly by experienced nurse

Main outcome variables
Sedation velocity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170212032528N2**
Registration date: **2018-12-10, 1397/09/19**
Registration timing: **retrospective**

Last update: **2018-12-10, 1397/09/19**
Update count: **0**

Registration date
2018-12-10, 1397/09/19

Registrant information

Name
Delaram Eghtesadi

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date
2016-06-21, 1395/04/01

Expected recruitment end date
2017-02-03, 1395/11/15

Actual recruitment start date
2016-06-21, 1395/04/01

Actual recruitment end date
2017-02-03, 1395/11/15

Trial completion date
empty

Scientific title
The Comparison of Sedation Induction Time of

Haloperidol, Perphenazine, Chlorpromazine, Promethazine, Trifluoperazine on Aggressive Patients

Public title
The Comparison of Sedation Induction Time of Haloperidol, Perphenazine, Chlorpromazine, Promethazine, Trifluoperazine on Aggressive Patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age>18 Years Have consent to enter the study by patient accompaniment Have no Contraindication for Interventional Drug (For Instance Muscle Rigidity and Neuroleptic Malignant Syndrome) Having Verbal Violence in the Time of First Visit Having Physical Violence in the Time of First Visit
Exclusion criteria:
Patient Family's Refuse for Collaboration After the First Agreement
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **76**
Actual sample size reached: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients were randomly divided into four groups by a psychiatric resident who participated in this study, using the same simple method. The ampoules of Haloperidol, Promethazine, Chlorpromazine, and Trifluoperazine, were labeled as 1 to 4. To divide patients into 4 groups we used Table of Random Numbers from 1 to 4.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hezar Jerib Avenue
City
Isfahan
Province
Isfehan
Postal code
8871863348
Approval date
2016-05-21, 1395/03/01
Ethics committee reference number
Ir.mui.rec.1395.3.025

Health conditions studied

1

Description of health condition studied
Acute Aggression
ICD-10 code
F39
ICD-10 code description
Unspecified mood [affective] disorder

Primary outcomes

1

Description
Sedation Velocity
Timepoint
During the Intervention and 2 hours later after intervention
Method of measurement
Signs and Time of Aggression Registered list

Secondary outcomes

1

Description
Adverse Effects of Sedative Drug
Timepoint
One Hour after Injection
Method of measurement
Drug side effects check list

Intervention groups

1

Description
Intervention Group 1: Injection of 5mg Haloperidol (Exir, Tehran, Iran)
Category
Treatment - Drugs

2

Description
Intervention Group 2: Injection of 50 mg Chlorpromazine (TehranChemie, Tehran, Iran)

Category
Treatment - Drugs

3

Description
Intervention Group 3: Injection of 1 mg Trifluoperazine (Caspian Tamin, Gilan, Iran)
Category
Treatment - Drugs

4

Description
Intervention Group 4: Injection of 50 mg Promethazine (Alborz darou, Qazvin, Iran).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatry Urgency of Nour Hospital
Full name of responsible person
Delaram Eghtesadi, M.D
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Isfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash, M.D
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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
Vice chancellor for research of Isfahan 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
Isfahan University of Medical Sciences
Full name of responsible person
Delaram Eghtesadi, M.D
Position
Consultant
Latest degree
Specialist
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Ali Mousavi, M.D
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Professor

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Person responsible for updating data

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Medical School of Isfahan
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Psychiatry resident, Consultant
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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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available