

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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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Email address

bsrc@mui.ac.ir

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

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8871863348

Approval date

2016-05-21, 1395/03/01

Ethics committee reference number

lr.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

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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

Other areas of specialty/work

Psychiatrics

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Psychiatry department of Isfahan University of Medical Sciences

Full name of responsible person

Ali Mousavi, M.D

Position

Professor

Latest degree

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

Medical School of Isfahan

Full name of responsible person

Delaram Eghtesadi, M.D

Position

Psychiatry resident, Consultant

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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