

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Intravenous Haloperidol against intravenous Diazepam in improving conversion disorder in the emergency room

Protocol summary

Summary

The purpose of this study is to evaluate the effects of haloperidol versus diazepam in improving the clinical symptoms in patients with conversion disorder according to DSM IV criteria referred to emergency room. Patients who are referred to Imam Hossein hospital emergency room will be the population of this study. The total sample size will be 168 patients, including four groups of men and women with and without history of psychiatric illness. Groups will be matched for sex and history of psychiatric illness. All patients with conversion disorder according to DSM IV criteria who are referred to emergency room will be included in this study. However, patients with abnormal vital signs; illness; under 18 years; over 60 years; pregnant; addicted patients and those who are not willing to participate in this study will be excluded. Eligible patients who signed a consent form to participate and received a questionnaire to answer the following questions regarding to personal data, underlying diseases, history of psychiatric illness, drug history, recovery and discharge time. These patients will randomly receive an injection two doses (5 mg and 5-10 mg) of either haloperidol or diazepam by a nurse who would not communicate with the physicians involved . The patients will be monitored during the course of treatment and symptoms such as time of recovery and possible complications will be recorded by a physician. The patients will be follow up a week and any possible complications will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108317449N1**

Registration date: **2012-06-23, 1391/04/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-23, 1391/04/03

Registrant information

Name

Majid Shojaee

Name of organization / entity

Shahid Beheshti Medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 2380

Email address

m.shojaee@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti Medical University

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intravenous Haloperidol against intravenous Diazepam in improving conversion disorder in the emergency room

Public title

Intravenous Haloperidol efficacy in improving conversion disorder patients in emergency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with conversion disorder according to DSM IV criteria referred to emergency room.
Exclusion criteria: Patients with abnormal vital signs; ill; under 18; over 60; pregnant patients; opium addicted patients; Unwillingness to cooperation

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **168**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti Medical University, Medical School,
Ethics Committee

Street address

Shahid Beheshti University of Medical Science and
Health Care, Medical School, Koodakyar Deadlock,
Yemen St, Chamran Highway

City

Tehran

Postal code

Approval date

2012-04-29, 1391/02/10

Ethics committee reference number

90-1-134-8723-8303

Health conditions studied

1

Description of health condition studied

conversion disorder

ICD-10 code

F44

ICD-10 code description

Dissociative [conversion] disorders

Primary outcomes

1

Description

The patient feel better

Timepoint

Before the intervention, one hour after the intervention
and one week after intervention

Method of measurement

Standardized questionnaire, the patients feel better,
better expressed by the patient and his companions

2

Description

The patient's symptoms disappear

Timepoint

Before the intervention, one hour after the intervention
and one week after intervention

Method of measurement

Standardized questionnaire, the patients feel better,
better expressed by the patient and his companions

Secondary outcomes

1

Description

Drug side effects

Timepoint

Just after the intervention until a week later

Method of measurement

Questionnaire, Physical exam

2

Description

Worsening of the patient

Timepoint

Just after the intervention until a week later

Method of measurement

Questionnaire, Physical exam

3

Description

Treatment failure

Timepoint

Just after the intervention to one hour after the start of
intervention

Method of measurement

Physical examination

Intervention groups

1

Description

Haloperidol, 5mg, Intravenous

Category

Treatment - Drugs

2**Description**

Diazepam, 5-10mg, Intravenous

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam hossein Medical & Educational Center

Full name of responsible person

Dr Majid Shojaee

Street address

Emam hossein Medical & Educational Center, Shahid Madani st.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti Medical University

Full name of responsible person

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City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti Medical University

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Shahid Beheshti Medical University

Full name of responsible person

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Position

Assistant Professor of Emergency Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty