

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The investigation of the antipsychotic effects of adding d-penicillamine to risperidone on the positive and negative symptoms of schizophrenia.

Protocol summary

Study aim

the anti-psychotic effects of adding D-penicillamine to Risperidone on positive and negative symptoms of schizophrenia

Design

randomised control trial double blind

Settings and conduct

32 hospitalized patients in Zare hospital in Sari were selected and divided into two groups of 16 cases and control group based on stratified random sampling, so that each group included equal numbers of women and men.

Participants/Inclusion and exclusion criteria

Patients with schizophrenia aged 18-65 years who have not received an anti-psychotic in last week.

Intervention groups

32 hospitalized patients were selected and divided into two groups of 16 cases and control group based on stratified random sampling, so that each group included equal numbers of women and men.

Main outcome variables

age,gender,marriage,education, PANSS score

General information

Reason for update

Acronym

Positive and Negative Symptom Scale (PANSS)

IRCT registration information

IRCT registration number: **IRCT20131007014928N6**

Registration date: **2019-01-10, 1397/10/20**

Registration timing: **retrospective**

Last update: **2019-01-10, 1397/10/20**

Update count: **0**

Registration date

2019-01-10, 1397/10/20

Registrant information

Name

Mehdi Pourasghar

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Email address

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Recruitment status

Recruitment complete

Funding source

Providing Placebo and medication on behalf of Mazandaran university of medical science.

Expected recruitment start date

2017-09-21, 1396/06/30

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

2017-09-21, 1396/06/30

Actual recruitment end date

2017-11-21, 1396/08/30

Trial completion date

2017-11-21, 1396/08/30

Scientific title

The investigation of the antipsychotic effects of adding d-penicillamine to risperidone on the positive and negative symptoms of schizophrenia.

Public title

The investigation of the antipsychotic effects of adding d-penicillamine to risperidone on schizophrenia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with schizophrenia that did not receive any

antipsychotics during the last week.
Exclusion criteria:
Patient did not suffer from Wilson's or other metabolic diseases

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **32**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random tables

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, researchers and nurses were kept blind

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Sari-Neka road, Zare Hospital

City

sari

Province

Mazandaran

Postal code

8471674321

Approval date

2007-10-31, 1386/08/09

Ethics committee reference number

86-49

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

f20.0

ICD-10 code description

پارانویید

Primary outcomes

1

Description

Positive and negative symptoms.

Timepoint

weekly

Method of measurement

PANSS

Secondary outcomes

1

Description

Adverse effects.

Timepoint

weekly until 6 weeks.

Method of measurement

Simpson Angus Scale

Intervention groups

1

Description

16 patients in the case group were treated with oral risperidone (8-6 mg) per day for 6 weeks as a neuroleptic drug with d-penicillamine (1000 mg / day) and pyridoxine (100 mg / day).

Category

Treatment - Drugs

2

Description

Get it Sixteen patients in the control group are also given risperidone (6-8 mg daily) with pyridoxine (100 mg per os) and placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare Hospital Sari

Full name of responsible person

Dr Mehdi Pourasghar

Street address

7 km Sari Road to Neka

City

Sari

Province

Mazandaran

Postal code

4816788888

Phone

+98 11 3328 3886

Email

zarehospital@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mazandaran University of Medical Science.

Full name of responsible person

Deputy of research and technology

Street address

Imam Square , Jouybar Road

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3448 4800

Email

zarehospital@yahoo.com

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

Yes

Title of funding source

Mazandaran University of Medical Science.

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**

Mazandaran University of Medical Science.

Full name of responsible person

Dr Mehdi Pourasghar

Position

Assistant Professor/Fellowship of psychotherapy

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

Street address

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

Study Protocol

No - There is not 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