Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

D-Penicillamin Add-On Therapy Compared to Risperidone Alone in Schizophrenia: A Double-Blind, Randomized, Placebo-Controlled Clinical Trial

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study was to assess the effects of D-penicillamine add on risperidone on positive and negative symptoms of schizophrenia. Thirty two in-patients with schizophrenia (paranoid and non-paranoid) are assigned to the intervention or control group. The patients in the intervention group receive 6 to 8 mg risperidon plus 1000 mg/day of D-penicillamine and 100mg/day piridoxine and in the control group receive the same dose of risperidone plus placebo and 100mg/day piridoxine for 6 weeks. Psychotic symptoms were assessed by Positive and Negative Syndrome Checklist (PANSS) weekly. Serum level of seroloplasmin was checked before and after the trial. Extra-pyramidal Side effects were also evaluated using Simpson-Angus Rating Scale weekly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801241457N4**
Registration date: **2010-11-02, 1389/08/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-11-02, 1389/08/11

Registrant information

Name

Mehran Zarghami

Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences and Department of Psychiatry, Mazandaran Univ

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences and Health Services

Expected recruitment start date

2007-01-20, 1385/10/30

Expected recruitment end date

2008-01-20, 1386/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

D-Penicillamin Add-On Therapy Compared to Risperidone Alone in Schizophrenia: A Double-Blind, Randomized, Placebo-Controlled Clinical Trial

Public title

D-Penicillamin Add-On Therapy Compared to Risperidone Alone in Schizophrenia: A Double-Blind, Randomized, Placebo-Controlled Clinical Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of schizophrenia according to DSM-IV-TR with two physicians Exclusion criteria: hepatic failure, renal failure, malignancies, pregnancy, drug

addiction

Age
From **18 years** old to **56 years** old

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mazandaran University of Medical Sciences

Street address
Vice Chancellor of Research-Mazandaran University of Medical Sciences, Moallem Square

City
Sari

Postal code
4817844718

Approval date
2007-10-09, 1386/07/17

Ethics committee reference number
87-88

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
severity of symptoms

Timepoint
weekly

Method of measurement
PANSS

Secondary outcomes

1

Description
Faster response to risperidone and side effects

Timepoint
weekly

Method of measurement
PANSS, Liver Function Laboratory Tests, and checklist

Intervention groups

1

Description
Risperidone, 6-8 mg, orally, plus D-penicillamine, 1000 mg/day, and Piridoxine, 100 mg/day, for 6 weeks

Category
Treatment - Drugs

2

Description
Risperidone, 6-8 mg, orally, plus Placebo, 1000 mg/day, and Piridoxine, 100 mg/day, for 6 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Zare Hospital

Full name of responsible person
Dr. Mehdi Pourasghar

Street address
Zare Hospital, Neka Road

City
Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr Seyed Jalal Hoseini Mehr

Street address

Vice Chancellor of Research, Mazandaran University of Medical Sciences, Moallem Square

City
Sari

Grant name
10506

Grant code / Reference number
10506

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mazandaran University of Medical Sciences

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
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Mehdi Pourasghar

Position
Psychiatrist

Other areas of specialty/work

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Web page address

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