

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Zinc Sulfate 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 is to assess the effects of zinc supplementation add on risperidone on positive and negative symptoms of schizophrenia. Thirty patients who are stratified according to age, gender and subtype of schizophrenia (paranoid and non-paranoid) will be assigned to treatment with 8 to 10 mg Risperidon plus three 220 mg capsules of zinc sulfate per day or the same dose of risperidone plus placebo for 6 weeks. Psychotic symptoms will be assessed by Positive and Negative Syndrome Checklist (PANSS) in week 0, 2, 4, and 6. Data are analyzed by repeated measure ANOVA, and Newman-Keuls with graph pad.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801241457N3**

Registration date: **2011-06-07, 1390/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-07, 1390/03/17

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)

Phone

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mzarghami@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2008-03-15, 1386/12/25

Expected recruitment end date

2009-07-16, 1388/04/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Zinc Sulfate add-on therapy compared to risperidone alone in schizophrenia: a double-blind, randomized, placebo-controlled clinical trial

Public title

Zinc Sulfate add-on therapy compared to risperidone alone in schizophrenia: a double-blind, randomized, placebo-controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: DSM-IV-TR criteria for schizophrenia, PANSS score more than 80, no anti psychotic consumption or seven half-life, the drug was wash out
Exclusion criteria: other psychiatric disorders such as substance dependence and physical illnesses, such as liver and renal failure, cardiovascular diseases, allergic

and immune system disorders etc.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

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**

Ethics committee, Vice Chancellor of Research

Street address

moalem sq.

City

sari

Postal code

4817844718

Approval date

2007-03-12, 1385/12/21

Ethics committee reference number

86-84

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20.9

ICD-10 code description

Schizophrenia, unspecified

Primary outcomes**1****Description**

Severity of symptoms

Timepoint

Baseline and 2nd, 4th, and 6th week

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes**1****Description**

The speed of risperidone antipsychotic effect

Timepoint

Baseline and 2nd, 4th, and 6th week

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

Intervention groups**1****Description**

Prescription of 8 to 10 mg oral risperidone plus three 220 mg oral capsules of zinc sulfate per day for 6 weeks

Category

Treatment - Drugs

2**Description**

Prescription of 8 to 10 mg oral risperidone plus three 220 mg oral capsules of placebo per day for 6 weeks

Category

Placebo

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

Zare Hospital

Full name of responsible person

Mehran Zarghami

Street address

Zare Hospital, Neka Road

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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

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Vice Chancellor of Research, Moallem Square

City

Sari
Grant name
86-84
Grant code / Reference number
86-84
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
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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