Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

+98 15 1328 5659

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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

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, 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
Mazandaran University of Medical Sciences

Full name of responsible person
Mehran Zarghami

Position
Professor

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