

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2026

Beneficial Antipsychotic Effects of Ascorbic Acid Add-On Therapy Compared to Haloperidol Alone in Schizophrenia, (A Randomized, Double-blind, Placebo-Controlled Clinical Trial)

Protocol summary

Summary

The aim of this study is to investigate the effect of ascorbic acid Add-On compared to Haloperidol alone in schizophrenia. A total of 50 patients with schizophrenia admitted to Zare hospital of Sari are randomly assigned into intervention or control group to receive haloperidol 15-30 mg/day plus ascorbic acid 400 mg/day or the same dose of haloperidol plus placebo for 6 weeks. Psychotic symptoms are assessed weekly by Positive and Negative Syndrome Scale for 6 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809201457N7**

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)

Phone

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2003-04-03, 1382/01/14

Expected recruitment end date

2006-08-03, 1385/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Beneficial Antipsychotic Effects of Ascorbic Acid Add-On Therapy Compared to Haloperidol Alone in Schizophrenia, (A Randomized, Double-blind, Placebo-Controlled Clinical Trial)

Public title

Beneficial Antipsychotic Effects of Ascorbic Acid Add-On Therapy Compared to Haloperidol Alone in Schizophrenia, (A Randomized, Double-blind, Placebo-Controlled Clinical Trial)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: DSM-IV-TR criteria for schizophrenia, Informed consent of the patients and their tutor, living in the southern coastwise of the Caspian sea, Hospitalization in Zare Hospital Exclusion criteria: Treatment resistance schizophrenia

Age

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

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 40

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 of Mazandaran University of
Medical Sciences

Street address

Moallem Square

City

Sari

Postal code

4817844718

Approval date

2002-07-02, 1381/04/11

Ethics committee reference number

31-81

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Symptoms of schizophrenia

Timepoint

weekly

Method of measurement

Brief Psychiatric Rating Scale (BPRS)

Secondary outcomes

1

Description

Faster response to haloperidol and side effects

Timepoint

weekly

Method of measurement

Brief Psychiatric Rating Scale (BPRS) and clinical
interview and examination

Intervention groups

1

Description

Haloperidol, 20 mg/day, orally, plus Ascorbic acid, 1500
mg/day, for 6 weeks, Biperiden (up to 6 mg/day) and
lorazepam tablets were available for extra-pyramidal
side effects and agitation or anxiety respectively

Category

Treatment - Drugs

2

Description

Haloperidol, 20 mg/day, orally, plus Placebo, for 6 weeks,
Biperiden (up to 6 mg/day) and lorazepam tablets were
available for extra-pyramidal side effects and agitation or
anxiety respectively

Category

Treatment - Drugs

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

Moallem Square

City

Sari

Grant name
10506

Grant code / Reference number
31-81

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