

# 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

+98 15 1328 5659

##### Email address

mzarghami@mazums.ac.ir

##### 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**

**Street address**  
Zare Hospital, Neka Road

**City**  
Sari

**Postal code**  
4815466848

**Phone**  
+98 15 1328 5659

**Fax**  
+98 15 1328 5109

**Email**  
mzarghami@mazums.ac.ir &  
mehran.zarghami@gmail.com

**Web page address**

## Person responsible for scientific 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**

**Street address**  
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mehran.zarghami@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences

**Full name of responsible person**  
Mehran Zarghami

**Position**  
Professor

**Other areas of specialty/work**

**Street address**  
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## 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*