

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of concomitant psychotropic medication and electroconvulsive therapy on Schizophrenia

#### Protocol summary

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##### Summary

This is a double blind randomized control clinical trial about the safety and efficacy of concomitant Electroconvulsive therapy and atypical antipsychotics in patients with schizophrenia. The sample includes 60 patients with schizophrenia randomly allocated to one of the groups. The Positive and Negative Syndrome Scale (PANSS) is used for assessment of treatment efficacy. Need to receive electroconvulsive therapy (ECT) determined by psychiatrist is an inclusion criteria. Patient or caregivers who do not provide written informed consent are excluded. Patients with serious medical conditions are not included.

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2011-07-14, 1390/04/23

##### Expected recruitment end date

2012-11-14, 1391/08/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201107143930N7**

Registration date: **2011-08-09, 1390/05/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-08-09, 1390/05/18

##### Registrant information

###### Name

Ahmad Ghanizadeh

###### Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1627 3070

###### Email address

##### Scientific title

The effect of concomitant psychotropic medication and electroconvulsive therapy on Schizophrenia

##### Public title

Concomitant psychotropic medication and electroconvulsive therapy on Schizophrenia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusive criteria: Diagnosed schizophrenia in accordance with DSM-IV, needs to be applied electroconvulsive therapy (ECT) determined by psychiatrist; providing written informed consent. Exclusion Criteria: Patient who does not volunteer himself or herself, Serious neurological or medical damage such as epilepsy, diabetes, cardiac disease or autistic disorder.

##### Age

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

##### Gender

Both

##### Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## 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 Shiraz University of Medical Sciences

##### Street address

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

##### City

Shiraz

##### Postal code

#### Approval date

2011-09-29, 1390/07/07

#### Ethics committee reference number

CT-90-2974

## Health conditions studied

### 1

#### Description of health condition studied

schizophrenia

#### ICD-10 code

F20

#### ICD-10 code description

Schizophrenia

## Primary outcomes

### 1

#### Description

The Positive and Negative Syndrome Scale for schizophrenia (PANSS)

#### Timepoint

before first ECT session and about 4 weeks after the last session of ECT

#### Method of measurement

Interview

## Secondary outcomes

### 1

#### Description

a modified version of Mini Mental Status Evaluation

#### Timepoint

before first ECT session, after every session of ECT, and about 4 weeks after the last session of ECT

#### Method of measurement

interview

## Intervention groups

### 1

#### Description

Olanzapin (5 to 20 mg/day) or respredone (1 to 6 mg/day)

#### Category

Treatment - Drugs

### 2

#### Description

Placebo

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences

##### Full name of responsible person

Ahmad Ghanizadeh

##### Street address

Hafez hospital, Chamran Street

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

##### Full name of responsible person

Gholam Reza Hatam

##### Street address

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

##### City

Shiraz

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

**organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Shiraz 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical sciences

**Full name of responsible person**

Ahmad Ghanizadeh

**Position**

MD

**Other areas of specialty/work****Street address**

Hafez Hospital, Chamran Street

**City**

Shiraz

**Postal code****Phone**

+98 71 1627 3070

**Fax****Email**

ghanizad@sina.tums.ac.ir

**Web page address****Person responsible for updating data****Contact****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*