

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effectiveness of Topiramate augmentation compared with placebo in chronic schizophrenia admitted to Ebnesina and Hejaze Hospitals in Mashad

#### Protocol summary

##### Summary

Objectives & aims: The limitations of antipsychotics for treatment of schizophrenia have led to the investigation of the usefulness of pharmacological augmentation strategies. Clinical studies have provided evidence for glutamate abnormalities in schizophrenia. Topiramate is an anticonvulsant drug with AMPA receptor antagonist properties; therefore, the objective of the present study was to explore the therapeutic efficacy of topiramate as an adjunctive medication in schizophrenia. Materials & Method: A 17 weeks, double-blind, placebo-controlled clinical trial was performed on eighty patients aged 25- to 65-year-old in 2005-2007. All were hospitalized in Mashhad psychiatric hospitals with chronic-treatment Resistant DSM-IV-TR-diagnosed schizophrenia. Up to 300 mg/day of clozapine was administered to all participants. Topiramate (200-300 mg/day) or placebo was gradually added to their ongoing treatment randomly. Efficacy of medication was measured by administering PANSS at baseline and weeks 4, 8, 12 and 17 and compared in the two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138904014236N1**

Registration date: **2006-03-21, 1385/01/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2006-03-21, 1385/01/01

##### Registrant information

Name

Fatemeh Behdani

##### Name of organization / entity

Mashad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1711 2723

##### Email address

behdanif@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

mashad university of medical sciences

##### Expected recruitment start date

2006-03-21, 1385/01/01

##### Expected recruitment end date

2007-05-22, 1386/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effectiveness of Topiramate augmentation compared with placebo in chronic schizophrenia admitted to Ebnesina and Hejaze Hospitals in Mashad

##### Public title

Effect of Topiramate in treatment of chronic schizophrenia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria 1. All the patients who meet the full criteria of chronic and treatment resistant schizophrenia disorder, based on DSMIV-TR 2. Ages of subjects were

between 25 to 65 years 3. All patients were hospitalized for at least 6 month before the study 4. All patients were being treated with Clozapin Exclusion criteria 1. Chronic diseases including diabetes, hypertension, history of kidney stone, epilepsy and substance abuse 2. An ongoing medical treatment 3. Elevated PANSS score up to 30% 4. Adverse effects associated with therapy including dizziness, agitation, hypertension, allergy to medications 5. Medical problems need to be treated such as diarrhea, urinary infection, cardiovascular disease, and trauma. 6. Temporary or permanent discharge from hospital while in study 7. Developing new psychiatric symptoms such as manic or hypomanic episode, panic attack

#### Age

From **25 years** old to **65 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### 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

Mashad university of medical sciences

##### Street address

Daneshgah Ave. Ghoreishi Building

##### City

Mashad

##### Postal code

#### Approval date

2006-02-05, 1384/11/16

#### Ethics committee reference number

1897-ح

## Health conditions studied

### 1

#### Description of health condition studied

Schizophrenia

#### ICD-10 code

F20

#### ICD-10 code description

Schizophrenia

## Primary outcomes

### 1

#### Description

Positive symptoms

#### Timepoint

week 0, 4, 8, 12 and 17

#### Method of measurement

Positive and Negative Syndrome Scale (PANSS)

### 2

#### Description

Negative Symptoms

#### Timepoint

week 0, 4, 8, 12 and 17

#### Method of measurement

Positive and Negative Syndrome Scale(PANSS)

### 3

#### Description

General Psychopathology

#### Timepoint

week 0, 4, 8, 12 and 17

#### Method of measurement

Positive and Negative Syndrome Scale(PANSS)

## Secondary outcomes

### 1

#### Description

Side effects

#### Timepoint

week 4, 8, 12 and 17

#### Method of measurement

checklist

## Intervention groups

### 1

#### Description

Optimum dosage of clozapine was continued for all participants for 4 weeks and then topiramate was gradually added to their ongoing treatment. Topiramate was prescribed at a dose of 50 mg on day 0. Every 2 days, the dose was increased by 50 mg/day and based on tolerability. The maximum dose allowed was 150 mg twice a day. Subjects were maintained on topiramate for 8 weeks, thereafter they were tapered and discontinued

gradually in 1 week. They were followed for an additional 4 weeks on their stable antipsychotic medications.

**Category**

Treatment - Drugs

**2****Description**

Optimum dosage of clozapine was continued for all participants for 4 weeks and then placebo (was as same as topiramate in the shape and color) was gradually added to their ongoing treatment. Subjects were maintained on placebo for 8 weeks, thereafter they were tapered and discontinued gradually in 1 week. They were followed for an additional 4 weeks on their stable antipsychotic medications.

**Category**

Placebo

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

Ebnesina Hospital

**Full name of responsible person**

Fatemeh Behdani

**Street address**

Horre Amel Bulevard

**City**

Mashad

**2****Recruitment center****Name of recruitment center**

Hejaze Hospital

**Full name of responsible person**

Fatemeh Behdani

**Street address**

Khajeh Rabei

**City**

Mashad

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashad university of medical sciences

**Full name of responsible person**

Dr Monavar Afzalagae

**Street address**

Daneshgah Ave., Goraishi Building, vice chancellor for research

**City**

Mashad

**Grant name**

0000

**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashad 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**

Mashad University of Medical Sciences

**Full name of responsible person**

Fatemeh Behdani

**Position**

Psychiatrist, Associate Professor

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

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashad University of Medical Sciences

**Full name of responsible person**

Paria Hebrani

**Position**

Associate Professor, Psychiatrist

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

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**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*