

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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

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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-ت

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 Buildding, 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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Paria Hebrani

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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