

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Efficacy of Topiramate in the treatment of Schizophrenia

Protocol summary

Summary

The aim of research is the study of Topiramate in the treatment of schizophrenia .Method of research is randomized ,triple blind ,placebo controlled clinical trial .Study population are inpatient and outpatient schizophrenic patients referred to Amirkabir Hospital and Imamreza clinic . Inclusion criteria:age range 15-50 ;diagnosis of schizophrenia according to DSM4-TR criteria and clinical interview by psychiatrist ; informed written consent letter; a score of at least 60 in PANSS Exclusion criteria :pregnancy;lactation; substance abuse;severe physical disease;epilepsy;use of Antiepileptic drugs ;contraindication of Topiramate Patients are randomly divided in two groups (intervention and control).Each group receive an atypical antipsychotic for 12 weeks .In addition to antipsychotic ,intervention group receive Topiramate 200mg/day ,and control group receive placebo.The time of intervention is 12 weeks from the start date.Primary outcome is change in PANSS scores.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201303287373N3**

Registration date: **2013-04-08, 1392/01/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-08, 1392/01/19

Registrant information

Name

Hamidreza Jamilian

Name of organization / entity

Arak University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Arak university of Medical Sciences vice president of education and research

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Topiramate in the treatment of Schizophrenia

Public title

Efficacy of Topiramate in the treatment of Schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:age range 15-50 ;diagnosis of schizophrenia according to DSM4-TR criteria and clinical interview by psychiatrist ; informed written consent letter; a score of at least 60 in PANSS Exclusion criteria :pregnancy;lactation; substance abuse;severe physical disease;epilepsy;use of Antiepileptic drugs ;contraindication of Topiramate

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

Groups that have been masked*No information***Sample size**Target sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Arak University of Medical Sciences

Street address

basij square

City

Arak

Postal code

3819691187

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

15-141-91

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes**1****Description**

PANSS

Timepoint

before intervention and every 4 weeks

Method of measurement

clinical examination

Secondary outcomes**1****Description**

extrapyramidal side effects

Timepoint

before intervention and every 4 weeks

Method of measurement

clinical examination

Intervention groups**1****Description**

Intervention group recieve an atypical antipsychotic(equivalent to Olanzapine 20 mg/day) plus Topiramate 200 mg/day for 12 weeks .

Category

Treatment - Drugs

2**Description**

Control group recieve an atypical antipsychotic(equivalent to Olanzapine 20 mg/day) plus placebo for 12 weeks.

Category

Treatment - Drugs

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

Amirkabir Hospital

Full name of responsible person

Hamidreza Jamilian

Street address

Amirkabir Hospital

City

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

Arak University Medical of Sciences

Full name of responsible person

Dr.Ashtiany

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Basij square

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor**

organization/entity?

Yes

Title of funding source

Arak University Medical of 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**

Arak University of Medical Sciences

Full name of responsible person

Hamidreza Jamilian

Position

Board of Psychiatry, Assistant professor

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

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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