Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Zonisamide for prevention of Atypical (Second generation) antipsychotics associated weight gain in schizophrenia : A double- blind, placebo controlled trial

Protocol summary

Summary

This is a double- blind, randomized placebo controlled trial to investigate the possible effect of zonisamide on prevention of weight gain in patients with schizophrenia taking atypical antipsychotics. The participants are 56 patients that they will be allocated to one of the two parallel groups. One group takes zonisamide (up to 150 mg/day) plus antipychotics. The other group will receive antipsychotic plus placebo. Duration of this study is 10 weeks. Assessment includes evaluation of height, weight, and waist circumference. The patients will be assessed at pre-intervention, week 4, week 8, and week 10 after intervention onset. Patients with schizophrenia administered atypical antipsychotics are included. Those with a marked medical condition will be excluded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103283930N5**
Registration date: **2011-07-13, 1390/04/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-13, 1390/04/22

Registrant information

Name
Ahmad Ghanizadeh
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Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2011-03-28, 1390/01/08

Expected recruitment end date

2012-03-27, 1391/01/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Zonisamide for prevention of Atypical (Second generation) antipsychotics associated weight gain in schizophrenia : A double- blind, placebo controlled trial

Public title

Zonisamide for prevention of Atypical (Second generation) antipsychotics associated weight gain in schizophrenia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria are: age range of 16 to 65; lack of any reported neurological disease; lack of reported thyroid function problem; lack of current active substance use; lack of taking medication leading to significant weight gain or loss; no taking sulfanomides; lack of self reported kidney stone. Exclusion criteria are: lack of providing

written consent; any serious medical condition such as epilepsy, thyroid function problems, diabetes; breast feeding; pregnancy; any special nutritional regime or intensive exercise program to decease weight.

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: **56**

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 for Research, Shiraz University of Medical sciences, Zand Street

City
Shiraz

Postal code

Approval date
2011-03-15, 1389/12/24

Ethics committee reference number
Ct-89-5460

Health conditions studied

1

Description of health condition studied
schizophrenia

ICD-10 code
F20

ICD-10 code description
Schizophrenia

Primary outcomes

1

Description
hight

Timepoint
preintervention, weeks of 4, 8, and 10

Method of measurement
centimeter

2

Description
Weight

Timepoint
preintervention, weeks of 4, 8, and 10

Method of measurement
kilogram

3

Description
waist circumference

Timepoint
preintervention, weeks of 4, 8, and 10

Method of measurement
Centimeter

Secondary outcomes

empty

Intervention groups

1

Description
Zonisamide (150mg/day), Single dosage

Category
Treatment - Drugs

2

Description
Placeb

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

Street address

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

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

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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