Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of COMT Gene Polymorphisms and Response to Treatment and incidence of Extrapyramidal Side Effects in Schizophrenic Patients Treated with Olanzapine and Risperidone

Protocol summary

Summary

In this study we have evaluated the effect of the COMT gene polymorphism RS4680 comparing Olanzapine and Risperidone drug groups on the response to treatment and the incidence of extra pyramidal side effects (EPS) and other anti psychotic side effects. In this study, 61 patients with demonstrated schizophrenia in two Olanzapine and Risperidone treated groups were matched for different characteristics and we were monitored for eight weeks of the study. Inclusion criteria: schizophrenia with PANSS score more than 60; don't use anti psychotic drug one week before; IQ more than 70; don't use anti psychotic drug in 6 months ago; don't use Electrocardiography Therapy in one month ago.Exclusion criteria: psychiatric disorders in axis 1 and 2; Suicide and other plumbing; addiction in 6 months ago; severe drug side effects Response to treatment and extra pyramidal side effects was evaluated by PANSS and ESRS-Aforms respectively. A list containing common multiple drugs side effects were used to assess some common complications.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012520258N29**
Registration date: **2017-02-10, 1395/11/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor Research ,Arak University of Medical Sciences

Expected recruitment start date

2014-05-06, 1393/02/16

Expected recruitment end date

2015-05-06, 1394/02/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of COMT Gene Polymorphisms and Response to Treatment and incidence of Extrapyramidal Side Effects in Schizophrenic Patients Treated with Olanzapine and Risperidone

Public title

Effect of gen for Schizophrenic Patients Treated with drug

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: schizophrenia with PANSS score more

than 60; don’t use anti psychotic drug one week before; IQ more than 70; don’t use anti psychotic drug in 6 months ago; don’t use Electrocardiography Therapy in one month ago Exclusion criteria: psychiatric disorders in axis 1 and 2; Suicide and other plumbing; addiction in 6 months ago; severe drug side effects

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **61**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Arak University Of Medical Sciences

Street address
Dr Mohammad Rafiei, Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City
Arak

Postal code
38149578558

Approval date
2014-05-05, 1393/02/15

Ethics committee reference number
93-162-13

Health conditions studied

1

Description of health condition studied
Schizophrenia

ICD-10 code
F06.2

ICD-10 code description
Organic delusional [schizophrenia-like] disorder

Primary outcomes

1

Description
Response to treatment

Timepoint
after 8 week treatment

Method of measurement
PANSS form

2

Description
extra pyramidal side effects

Timepoint
after 8 week treatment

Method of measurement
ESRS-A form

3

Description
drugs side effects

Timepoint
after 8 week treatment

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We prescribe 2-12 milligram Risperidone daily.

Category
Treatment - Drugs

2

Description
Intervention group: We prescribe 5-25 milligram Olanzapine daily.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir hospital

Full name of responsible person
Dr Bahman Salehi

Street address
Amirkabir hospital, Parastar Square, Arak

City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Rafiee
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Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
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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
Vice chancellor for research, Arak 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

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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