

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of COMT Gene Polymorphisms and Response to Treatment and incidence of Extrapyrimal 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

Name

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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 Extrapyrimal 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 squire, 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

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Amirkabir hospital, Parastar Square, Arak

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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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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

Contact

Name of organization / entity
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Person responsible for updating data

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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