

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### 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

##### Street address

Amirkabir hospital, Parastar Square, Arak

**City**  
Arak

fa.farokhi@gmail.com  
**Web page address**

## 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

**Street address**  
Vice chancellor for research, Payambar Azam  
Complex, Basij square, Sardasht, Arak

**City**  
Arak

**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**  
Arak University of Medical Sciences

**Full name of responsible person**  
Dr seyed Yousef Shahtaheri

**Position**  
Resident of Anesthesiology

**Other areas of specialty/work**

**Street address**  
Medicine department, Payambar Azam complex, Basij  
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## Person responsible for scientific inquiries

#### Contact

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Faculty, psychologist

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## Person responsible for updating data

#### Contact

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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*