

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The efficacy of anti - toxoplasma drugs in the treatment of schizophrenia , a triple - blind, randomized , placebo-controlled clinical trial

#### Protocol summary

##### Summary

The aim of research is the study of efficacy of Anti-toxoplasma drugs in the treatment of schizophrenia . The method of research is randomized ,triple blind ,placebo controlled clinical trial. Study population are inpatient schizophrenic inpatient referred to Amirkabir Hospital . Inclusion criteria :informed written consent; diagnosis of schizophrenia according to DSMIV \_TR criteria and clinical interview by psychiatrist; a score of at least 60 in PANSS; age range 15-55 Exclusion criteria: pregnancy; lactation ; substance abuse; severe physical disease; contraindication of cotrimoxazole 200 patients are randomly divided in 2 groups (intervention and control).Both groups receive Risperidone 6 mg/day for 8 weeks .In addition to Risperidon ,intervention group receive Cotrimoxazole 960 mg twice daily, and control group receive placebo for 8 weeks .Primary outcome is change in PANSS scores .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201303287373N4**

Registration date: **2013-05-06, 1392/02/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-05-06, 1392/02/16

##### Registrant information

###### Name

Hamidreza Jamilian

###### Name of organization / entity

Arak University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 1222 5758

###### Email address

jamilian.hr@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Arak University of Medical Sciences (Dr. Ashtiani)

##### Expected recruitment start date

2013-05-01, 1392/02/11

##### Expected recruitment end date

2013-10-01, 1392/07/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of anti - toxoplasma drugs in the treatment of schizophrenia , a triple - blind, randomized , placebo-controlled clinical trial

##### Public title

The efficacy of anti - toxoplasma drugs in the treatment of schizophrenia , a triple - blind, randomized , placebo-controlled clinical trial

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria :informed written consent ;diagnosis of schizophrenia according to DSMIV \_TR criteria and clinical interview by psychiatrist ;a score of at least 60 in PANSS;age range 15-55 Exclusion criteria: pregnancy ; lactation ;substance abuse; severe physical disease ; contraindication of cotrimoxazole

##### Age

From **15 years** old to **55 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: **200**

**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****Approval date**

2013-02-06, 1391/11/18

**Ethics committee reference number**

92-143-2

**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 2 weeks

**Method of measurement**

clinical examination

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

extrapyramidal and skin side effects

**Timepoint**

before intervention and every 2 weeks

**Method of measurement**

clinical examination

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

Intervention group receive risperidone 6 mg/day plus cotrimoxazole 960 mg twice daily for 8 weeks .

**Category**

Treatment - Drugs

**2****Description**

Control group receive risperidone 6 mg/day plus placebo for 8 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**

Arak

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

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Ashtiani

**Street address**

Basij square

**City**

Arak

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

**organization/entity?**

Yes

**Title of funding source**

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**

Hamidreza Jamilian

**Position**

board of psychiatry,assistant professor

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

Amiakabir Hospital

**City**

Arak

**Postal code****Phone**

+98 8619181615442

**Fax****Email**

mjamilian@yahoo.com

**Web page address****Person responsible for scientific 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**

Amirkabir Hospital

**City**

Arak

**Postal code****Phone**

+98 86 1313 4715

**Fax****Email**

mjamilian@yahoo.com

**Web page address****Person responsible for updating data****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**

Amirkabir Hospital

**City**

Arak

**Postal code****Phone**

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**Fax****Email****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*