

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

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Position

board of psychiatry,assistant professor

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

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Full name of responsible person

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Position

board of psychiatry ,assistant professor

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

Amirkabir Hospital

City

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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