

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Minocycline as adjuvant therapy on negative symptoms in patients with chronic schizophrenia that are receiving risperidone: a double blind and placebo controlled randomized clinical trial

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of minocycline would improve psychopathology in subjects with stable schizophrenia treated with Risperidone. 40 patients with chronic DSM-IV-diagnosed schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=25) or 200 g/day of minocycline (N=25) for 8 weeks. Efficacy will be defined as the change from baseline to endpoint in score on the Positive and Negative Syndrome Scale (PANSS). Side effects will be also evaluated using checklist and Extra-pyramidal Symptoms Rating Scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202241556N34**

Registration date: **2012-03-01, 1390/12/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-03-01, 1390/12/11

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-03-05, 1390/12/15

Expected recruitment end date

2012-07-22, 1391/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Minocycline as adjuvant therapy on negative symptoms in patients with chronic schizophrenia that are receiving risperidone: a double blind and placebo controlled randomized clinical trial

Public title

Minocycline in the treatment of schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age between 18-50; Diagnosis of Schizophrenia based on DSM IV; chronic Schizophrenia(duration of the disorder>2 years); Stable on antipsychotics Exclusion Criteria: Substance dependence; IQ <70; any other mental disorder on axis I; Any serious medical or neurological problem ; receiving oral antipsychotic medications during the last week or receiving any depot antipsychotic medication during the last month; receiving ECT during the last 14 days; hepatic disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Keshvarz Blvd

City

Tehran

Postal code**Approval date**

2011-10-02, 1390/07/10

Ethics committee reference number

11921

Health conditions studied**1****Description of health condition studied**

schizophrenia

ICD-10 code

F20

ICD-10 code description

schizophrenia

Primary outcomes**1****Description**

Severity of schizophrenia

Timepoint

Baseline and weeks 2-4-6-8 after beginig of treatment

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

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

Tablets Risperidone (6 mg/day) combined with 200mg/day Minocycline as intervention group for 8 weeks

Category

Treatment - Drugs

2**Description**

Tablet Risperidone (6 mg/day) combined with placebo as control group for 8 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Roozbeh Hospital

Full name of responsible person

Dr. Shahin Akhondzadeh

Street address

South Kargar Sreet

City

Tehran

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

Tehran University of Medical Sciences

Full name of responsible person

Prof. Akbar Fotouhi

Street address

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

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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*