

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Fingolimod as an adjuvant therapy added to Risperidone in the treatment of schizophrenia : A randomized double blind and placebo controlled clinical trial

#### Protocol summary

##### Study aim

Investigating the therapeutic effect of Fingolimod in patients with schizophrenia

##### Design

Randomized double blind and placebo-controlled clinical trial

##### Settings and conduct

The study will be performed on patients with schizophrenia attending Roozbeh Hospital

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of schizophrenia based on DSM-5 - Minimum score of 60 based on PANSS - Age range: 18-60 years old - At least, 2 years have passed since the onset of the disorder. Exclusion criteria: Diagnosis of another disorder in axis II - Existence of a significant neurological or organic disease - IQ less than 70 based on interviewer clinical suspicion - Substance/drug dependence during the last 6 months (except nicotine and caffeine) - Use of antipsychotics during past 1 week or long-term antipsychotics during past 1 month - Receiving ECT during the last 2 weeks - Abnormal endocrine activity - Abnormal kidney and liver function - History of thrombosis and emboli - History of abnormal bleeding.

##### Intervention groups

Intervention group: Risperidone 2 mg, three times/day + Fingolimod 0.5 mg everyday for 8 weeks. Control group: Risperidone 2 mg, three times/day + Placebo tablet everyday for 8 weeks. Follow-up intervals for patients are at weeks 0, 4, and 8. Patients' improvement is evaluated based on PANSS and extra-pyramidal drug side effects are assessed based on ESRS, and side effects of Fingolimod are assessed at weeks 2, 4, and 8.

##### Main outcome variables

Severity of schizophrenia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20090117001556N137**

Registration date: **2021-08-01, 1400/05/10**

Registration timing: **prospective**

Last update: **2021-08-01, 1400/05/10**

Update count: **0**

##### Registration date

2021-08-01, 1400/05/10

##### 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

s.akhond@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-23, 1400/07/01

##### Expected recruitment end date

2023-09-23, 1402/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Fingolimod as an adjuvant therapy added to Risperidone in the treatment of schizophrenia : A randomized double blind and placebo controlled clinical trial

**Public title**

Fingolimod in the treatment of schizophrenia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diagnosis of schizophrenia based on DSM-5 Minimum score of 60 based on PANSS Age range: 18-60 years old At least, 2 years have passed since the onset of the disorder

**Exclusion criteria:**

Diagnosis of another disorder in axis II Existence of a significant neurological or organic disease IQ less than 70 based on interviewer clinical suspicion Substance/drug dependence during the last 6 months (except nicotine and caffeine) Use of antipsychotics during past 1 week or long-term antipsychotics during past 1 month Receiving ECT during the last 2 weeks Abnormal endocrine activity Abnormal kidney and liver function History of thrombosis and emboli History of abnormal bleeding

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups)

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

**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**

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2021-04-20, 1400/01/31

**Ethics committee reference number**

IR.TUMS.DDRI.REC.1400.018

**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 4 and 8

**Method of measurement**

By Positive and Negative Syndrome Scale (PANSS)

**Secondary outcomes**

empty

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

Intervention group: Risperidone 2 mg, three times/day +

Fingolimod 0.5 mg everyday for 8 weeks.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Risperidone 2 mg, three times/day +  
Placebo tablet everyday for 8 weeks.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Roozbeh hospital

**Full name of responsible person**

Prof. Mohammad Reza Mohammadi

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

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Tehran

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1333715914

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mohammadimr@tums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Ali Sahraian

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msahrai@tums.ac.ir

**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**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Shahin Akhondzadeh

**Position**

Professor of clinical psychopharmacology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

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**Email**

s.akhond@sina.tums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Prof. Shahin Akhondzadeh

**Position**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Shahin Akhondzadeh

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The data will be distributed through final report

**When the data will become available and for how long**

5 years from 2021 to 2026

**To whom data/document is available**

academic researchers

**Under which criteria data/document could be used**

users should cite the resource of data

**From where data/document is obtainable**

Prof Shahin Akhondzadeh

**What processes are involved for a request to access data/document**

by E mail

**Comments**