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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1333715914

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+98 21 5541 2222

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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

Street address

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

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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