

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

L-Theanine as an adjuvant therapy added to Risperidone for the treatment of patients with chronic schizophrenia: A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim

Investigating the effect of additive treatment of L-Theanine to Risperidone in patients with chronic schizophrenia

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Diagnosis of schizophrenia based on DSM-5. 2- Minimum score of 60 based on PANSS. 3- Age range: 18-55 years old. 4- At least, 2 years have passed since the onset of the disorder. Exclusion criteria: 1- Diagnosis of another disorder in axis II. 2- Existence of a significant neurological or organic disease. 3- IQ less than 70 based on interviewer clinical suspicion. 4- Substance/drug dependence during the last 6 months (except nicotine and caffeine). 5- Use of antipsychotics during past 1 week or long-term antipsychotics during past 1 month. 6- Receiving ECT during the last 2 weeks. 7- Abnormal endocrine activity. 8- Abnormal kidney and liver function. 9- History of trombosis and embolia. 10- History of abnormal bleeding.

Intervention groups

Intervention group: Risperidone 2 mg, three times/day + L-Theanine 400 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 severity of depression is evaluated based on Hamilton depression rating scale, and extra-pyramidal drug side effects are assessed based on ESRS, and side effects of L-Theanine are assessed based on a checklist with 25 items at weeks 2, 4, and 8.

Main outcome variables

Severity of schizophrenia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N133**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **prospective**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

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

2021-01-20, 1399/11/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

L-Theanine as an adjuvant therapy added to Risperidone for the treatment of patients with chronic schizophrenia: A randomized double blind and placebo controlled clinical trial

Public title

L-Theanine as an adjuvant therapy for chronic schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of schizophrenia based on DSM-5. Minimum score of 60 based on PANSS. Age range: 18-55 years. 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 trombosis and embolia. History of abnormal bleeding.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

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

2020-08-22, 1399/06/01

Ethics committee reference number

IR.TUMS.DDRI.REC.1399.034

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 (Johnson co. Belgium) 2 mg, three times/day + L-Theanine (Institute of Medicinal Plants) 400 mg everyday for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Risperidone (Johnson co. Belgium) 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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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.,
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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

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