# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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

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**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
**City**
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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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**Email**
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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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**Other areas of specialty/work**
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## Person responsible for updating data

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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**