Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Pregnenolone in the treatment of women with chronic schizophrenia: a double blind randomized trial

Protocol summary

Summary

The objective of this randomized, double-blind, placebo controlled study is to test the hypothesis that the addition of Pregnenolone would improve psychopathology in subjects with schizophrenia treated with Risperidone. 50 female patients with chronic schizophrenia will receive Risperidone (6 mg/day) combined with either placebo (N=25) or 50 mg/day of Pregnenolone (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: **IRCT201504211556N76**
Registration date: **2015-04-22, 1394/02/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-04-22, 1394/02/02

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

Tehran University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pregnenolone in the treatment of women with chronic schizophrenia: a double blind randomized trial

Public title

Pregnenolone in the treatment of women with chronic schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:1-women with Diagnosis of Schizophrenia based on DSM- 5 criteria; 2- Minimum Score of 60 on Positive and Negative Scale; 3- Age between 18-45; 4-Chronic Schizophrenia- duration of the disorder more than 2 years; 5-Minimum score of 20 in negative sub score. Exclusion criteria: 1-Any serious medical or neurological problem; 2- IQ less than 70; 3-Substance dependence during the last 6 months(except for nicotine and caffeine); 4-receiving oral antipsychotic medications during the last week or receiving any depot antipsychotic medication during the last month; 5-receiving ECT during the last 14 days ; 6-Hepatic and renal diseases; 7- History of thromboembolism ; 8-History of abnormal uterine bleeding, uterine or breast

canser; 9-CVA; 10-Hormone replacement therapy; 11-Endocrine abnormality.

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
4

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
2015-04-21, 1394/02/01

Ethics committee reference number
27746

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 2-4-8 after beginig of treatment

Method of measurement
Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes

empty

Intervention groups

1

Description
Tablet Risperidone (6 mg/day) combined with 50 mg/day Pregnenolone 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
Prof. Shahin Akhondzadeh

Street address
South Kregar street, Roozbeh Hospital

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr masoud yunesian

Street address
Keshvarz Blvd

City
Tehran

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

Other areas of specialty/work

Street address

South Kargar street; Roozbeh Hospital

City

Tehran

Postal code

Phone

+98 21 5541 2222

Fax

Email

s.akhond@sina.tums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

Street address

South Kargar Street; Roozbeh Hospital

City

Tehran

Postal code

Phone

+98 21 5541 2222

Fax

Email

s.akhond@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Prof. Shahin Akhondzadeh

Position

Prof. of Clinical Psychopharmacology

Other areas of specialty/work

Street address

South Karegar street; Roozbeh Hospital

City

Tehran

Postal code

Phone

+98 21 5541 2222

Fax

Email

s.akhond@sina.tums.ac.ir

Web page address

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