Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Combination of estrogen and antipsychotics in the treatment of women with chronic schizophrenia: a double-blind, randomized and placebo-controlled clinical trial

Protocol summary

Summary

This study designed to evaluate efficacy of conjugated estrogen in the treatment of patients with chronic schizophrenia. Participants in this study were 32 childbearing-aged women with chronic schizophrenia. These patients were hospitalized in an institute for chronically mentally ill patients. Participants were randomly divided into two groups: the first group (16 cases) received conjugated estrogen 0.625 mg/Day four weeks along with their previous antipsychotic regimen while the second group (16 cases) received adjunctive placebo plus antipsychotics. Positive and Negative Syndrome Scale (PANSS) used as measurement tool for assessment of psychopathology.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901283739N1**
Registration date: **2010-05-29, 1389/03/08**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-29, 1389/03/08

Registrant information

Name

Fateme Ghaderi

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1229 6827

Email address

ghaderifa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Yasuj University of Medical Sciences

Expected recruitment start date

2006-09-23, 1385/07/01

Expected recruitment end date

2007-09-23, 1386/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combination of estrogen and antipsychotics in the treatment of women with chronic schizophrenia: a double-blind, randomized and placebo-controlled clinical trial

Public title

Estrogen for schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: child-bearing age women with chronic schizophrenia, kept in Behravan institute, Yasuj Exclusion criteria: pregnancy, lactation, concurrent hormonal treatment, abnormal uterus bleeding, positive history of deep vein thrombosis, any serious neurologic disorders

Age

From **15 years** old to **45 years** old

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
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 Yasuj University of Medical Sciences
Street address
Jalil street, Yasuj, Iran
City
Yasuj
Postal code
75919-94799
Approval date
2006-02-01, 1384/11/12
Ethics committee reference number
84-11-6

Health conditions studied

1

Description of health condition studied
Schizophrenia
ICD-10 code
F20, F21,
ICD-10 code description
Schizophrenia, schizotypal and delusional disorders

Primary outcomes

1

Description
Schizophrenia symptoms
Timepoint
4 weeks
Method of measurement
PANSS

Secondary outcomes

empty

Intervention groups

1

Description
conjugated estrogen 0.625 mg/Day for four weeks
Category
Treatment - Drugs

2

Description
Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Behravan Rehabilitation Center
Full name of responsible person
Khodakaram Nikbakht
Street address
Besenjan
City
Yasuj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasuj University of Medical Sciences
Full name of responsible person
Dr. Moshfe Abdolali
Street address
Jalil st., Yasuj, Iran
City
Yasuj
Grant name
تحقیقات دانشگاهی
Grant code / Reference number
10506
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasuj 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
Yasuj University of Medical Sciences
Full name of responsible person
Ali Mohammadi
Position
Psychiatrist, Assistant Professor
Other areas of specialty/work
Street address
Jalil st., Yasuj, Iran
City
Yasuj
Postal code
75919-94799
Phone
+98 74 1223 0290
Fax
+98 74 1223 5153
Email
amohammadi@hotmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yasuj University of Medical Sciences
Full name of responsible person
Ali Mohammadi
Position
Psychiatrist, Assistant Professor
Other areas of specialty/work
Street address
Jalil st., Yasuj, Iran
City
Yasuj
Postal code
75919-94799
Phone
+98 74 1223 0290
Fax
+98 74 1223 5153
Email
amohammadi@hotmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Yasuj University of Medical Sciences
Full name of responsible person
Ali Mohammadi
Position
Psychiatrist, Assistant Professor
Other areas of specialty/work
Street address
Jalil st., Yasuj, Iran
City
Yasuj
Postal code
75919-94799
Phone
+98 74 1223 0290
Fax
+98 74 1223 5153
Email
amohammadi@hotmail.com
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