

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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

Besengan

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

تحقيقات 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**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

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Phone

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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

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Ali Mohammadi

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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