

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of therapeutic effects of Citalopram and Olanzapine with Citalopram and Aripiprazole in Schizophrenia patients.

Protocol summary

Summary

Schizophrenia is by all means a human tragedy. Not only for the patient but for the family and the community is the same. The purpose of this study will compare the effects of Citalopram treatment with Olanzapine and Citalopram with Aripiprazole in patients with Schizophrenia. This study will be a randomized clinical trial and population consist of all schizophrenia patients will be admitted to the psychiatric clinic of Fatemi Hospital in Ardabil from December until March 2014. In this study, all members will be selected for population and Patients will be randomly allocated into two treatment groups, Olanzapine with Citalopram and Aripiprazole with Citalopram. Patients and medicine providers will not know the name of the drug and Medications will be administered for eight weeks in both groups. After eight weeks, patients will complete the PANSS scale and brief psychiatric evaluation and Side effects will be reviewed for all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013090714577N1**
Registration date: **2014-12-06, 1393/09/15**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-06, 1393/09/15

Registrant information

Name

Abbas Naghizadeh- Baghi

Name of organization / entity

Ardabil University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of Citalopram and Olanzapine with Citalopram and Aripiprazole in Schizophrenia patients.

Public title

Effect of Olanzapine and Aripiprazole in schizophrenic patients

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Diagnosis of schizophrenia according to the criteria of DSM-IV-TR ; Referred to the psychiatric clinic Fatemi Hospital. Exclusion criteria: Individual or patient reluctance to participate in the study; History of other psychiatric disorders, patients who are currently treated with other drugs; History of known medical condition under treatment .

Age

From **18 years** old to **52 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ardabil University of Medical science

Street address

Daneshgah Street, Medical School, Ardabil University of Medical Sciences

City

Ardabil

Postal code

Approval date

2013-01-20, 1391/11/01

Ethics committee reference number

1025

Health conditions studied

1

Description of health condition studied

Schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

Primary outcomes

1

Description

Brief Psychiatric Rating Scale

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

individual's self-report

2

Description

Blood Pressure

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

mm/hg

3

Description

Weight

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Kg

4

Description

Positive and Negative Syndrome Scale

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Clinical Interview

5

Description

Insomnia

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation and Self-reported

6

Description

Anxiety

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation and Self-reported

7

Description

Drowsiness

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation and Self-reported

8

Description

Weakness

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation and Self-reported

9**Description**

Headache

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Self-reported

10**Description**

Restlessness

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation and Self-reported

11**Description**

Xerostomia

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation and Self-reported

12**Description**

Aggression

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation

13**Description**

Nausea

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation and Self-reported

14**Description**

Vomiting

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation and Self-reported

15**Description**

Tremor

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation and Self-reported

16**Description**

Extrapyramidal side effects

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Observation and Self-reported

17**Description**

Delusions

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Interview

18**Description**

Mental Turbulence

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Interview

19**Description**

Hallucinations

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Interview

20**Description**

Disorganized speech

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Interview

21**Description**

Chaotic behavior

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Interview

22**Description**

Incuriosity

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Interview

23

Description

Inability

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Interview

24

Description

Conservation

Timepoint

Pre-intervention and eight weeks after intervention

Method of measurement

Interview

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Citalopram(Sobhandarou) dose of 40mg/day plus Olanzapine (Sobhandarou) dose of 15mg per day for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: Citalopram(Sobhandarou) dose of 40mg/day plus Aripiprazole (Bakhtar-Bioshimi-Company) dose of 20mg per day for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi Hospital

Full name of responsible person

Javad Ghyami

Street address

Fatemi Hospital, Shariati Square, Ardabil

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Ardabil University of Medical Science

Full name of responsible person

Dr Hadi Piri

Street address

Daneshgah Street, Ardabil University of Medical Sciences

City

Ardabil

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Research deputy of Ardabil University of Medical Science

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

Ardabil University of Medical Sciences

Full name of responsible person

Javad Ghyami

Position

Medical Student

Other areas of specialty/work

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Full name of responsible person

Dr Fariba Sadeghi Movahed

Position

Psychiatrist

Other areas of specialty/work**Street address**

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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

Person responsible for updating data**Contact****Name of organization / entity**

Ardabil university of Medical Sciences

Full name of responsible person

Dr Abbas Naghizadeh-Baghi

Position

PhD in Physical Education

Other areas of specialty/work**Street address**

Medical School, Ardabil University of Medical