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

Country

Iran (Islamic Republic of)

Phone

+98 45 3323 0673

Email address

a.naghizadeh@arums.ac.ir

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
Street address
Daneshgah Street, Ardabil University of Medical Sciences, Medical School.
City
Ardabil
Postal code
5618953141
Phone
+98 41 1385 0951
Fax
Email
yalgiz.q@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr Fariba Sadeghi Movahed

Position
Psychiatrist
Other areas of specialty/work
Street address
Fatemi Hospital, Shariati Square, Ardabil
City
Ardabil
Postal code
5614733775
Phone
+98 45 1771 6187
Fax
Email
f.sadeghi.m@arums.ac.ir
Web page address

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 Sciences, Daneshgah Street, Ardabil
City
Ardabil
Postal code
5618953141
Phone
+98 45 1223 0673
Fax
Email
a.naghizade@arums.ac.ir
Web page address
htpp//www.arums.ac.ir

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