

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of the efficacy and safety of aripiprazole as an adjuvant to antipsychotics in patients with residual schizophrenia: A 12-week, randomized, double-blind, placebo-controlled clinical trial

Protocol summary

Summary

In this study, the aim is to determine whether adding Aripiprazole to the standard therapeutic regimen of schizophrenic patients could improve some aspects of the symptom burden or not. This study is a 12-week randomized, double-blind, placebo-controlled trial. Fifty patients with chronic stable schizophrenia with residual symptoms are randomly divided into the intervention and control groups. Simple randomization based on a random-numbers table is used to assign subjects to either the placebo or the intervention group. Subjects in the intervention group receive aripiprazole an initial dose of 10 mg/day for first week, which is increased to 15 mg/day on the second week and continue with the same dose until the end of the study along with their antipsychotic regimen. The control group receive their antipsychotic regimen alone for 12 weeks. Positive and Negative Syndrome Scale (PANSS), Clinical Global Impression of Severity (CGI-S), Clinical Global Impression of Improvement (CGI-I) and Hamilton Rating Scale for Depression (HRSD) are assessed at the baseline and on the third and sixth, eighth and twelfth weeks. All schizophrenic patients are managed based on the guidelines of the American Psychiatric Association. The diagnosis is made by two psychiatrists independently, according to the DSM-V criteria. During the study period, only co-medication with anticholinergic drugs and benzodiazepines are allowed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017013032236N3**

Registration date: **2017-02-13, 1395/11/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-13, 1395/11/25

Registrant information

Name

Narjes Hendouei

Name of organization / entity

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Country

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the efficacy and safety of aripiprazole as an adjuvant to antipsychotics in patients with residual schizophrenia: A 12-week, randomized, double-blind, placebo-controlled clinical trial

Public title

Aripiprazole effect in the treatment of residual symptoms in patients with schizophrenia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Male or female inpatients in two long-stay Psychiatric Care and Rehabilitation Centers which are Supervised by Iranian Rehabilitation Institute located in Sari in the north of Iran 2- 18-65 years at the time of screening 3- With a diagnosis of schizophrenia(paranoid, disorganized, catatonic, or undifferentiated type)or schizoaffective disorder, based on the Structured Clinical Interview for DSM-V and they are suffering from the disease for more than 2 years with residual symptomatology despite antipsychotic treatment 4- All patients are on antipsychotics for at least 1 year and a stable dose for at least 2 month are included in the trial and the antipsychotics dose remain unchanged during the trial. 5- Mood stabilizers (lithium and divalproex) and antidepressants (only the selective serotonin reuptake inhibitors (SSRIs) venlafaxine, and mirtazapine) were permitted as part of antipsychotic pharmacotherapy. Dose of these drugs must be stable for at least 2 month remain unchanged during the trial. Exclusions criteria: 1- Acute relapse (As acute relapse was defined an impending decompensation based on a PANSS score of ≥ 4 (moderately) on the subscore items of hostility and uncooperativeness and/or a $\geq 20\%$ increase in the PANSS total score. 2- Psychiatric comorbidity(primary or secondary diagnosis of bipolar I disorder, either manic or mixed episode, as defined by DSM-V) 3- History of substance dependence (including alcohol, but excluding nicotine) as defined by DSM-V and relapse within the past 6 months, or substance abuse within the 3 months preceding the trial or positive urine test for illicit drugs 4- Electroconvulsive therapy during the 6 past months 5- Suicidality(active suicide or homicide intent, or a suicide or homicide attempt in the preceding 6 months) 6- Mental retardation 7- Pregnant or at risk of pregnancy 8- Cognitive disorders such as dementia, delirium, or amnesia, traumatic brain injury 9- Current significant unstable medical illness (such as unstable cardiac disease, hepatic or renal impairment, evidence or history of malignancy or any significant hematological, endocrine)/ HIV infection / abnormalities on physical examination, vital signs, electrocardiogram (ECG), or clinical laboratory values 10- Hypersensitivity to aripiprazole 11- Previous treatment with aripiprazole in the past year 12- History of neuroleptic malignant syndrome 13- Unwilling or unable, in the opinion of the Investigator, to comply with study instructions

Age

From **18 years** old to **65 years** old

Gender

Both

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****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mazandaran University of Medical Sciences

Street address

Moallem street-Moallem square-Vice chancellor for research

City

Sari

Postal code**Approval date**

2016-09-22, 1395/07/01

Ethics committee reference number

IR.MAZUMS.REC.95.1475

Health conditions studied**1****Description of health condition studied**

Schizophrenia

ICD-10 code

F20

ICD-10 code description

F20.5

Primary outcomes**1****Description**

Severity of psychiatric symptoms assesment

Timepoint

Baseline and on the third and sixth ,eighth and twelfth weeks

Method of measurement

Positive and Negative Syndrome Scale (PANSS)

Secondary outcomes**1****Description**

Depressed mood assessment

Timepoint

Baseline and weeks 3, 6, 8 and 12

Method of measurement

Hamilton Rating Scale for Depression (HRSD)

2**Description**

Clinical Global Impression of Improvement (CGI-I)

Timepoint

Baseline and weeks 3, 6, 8 and 12

Method of measurement

Clinical Global Impression of Improvement (CGI-I)

3**Description**

Clinical Global Impression of Improvement (CGI-S)

Timepoint

Baseline and weeks 3, 6, 8 and 12

Method of measurement

Clinical Global Impression of Improvement (CGI-S)

4**Description**

Aripiprazole-induced induced akathisia assessment

Timepoint

Weekly

Method of measurement

Barnes Akathisia Scale

5**Description**

Aripiprazole-induced Movement disorder assessment

Timepoint

Weekly

Method of measurement

Abnormal Involuntary Movement Scale

Intervention groups**1****Description**

Subjects in the intervention group receive aripiprazole an initial dose of 10 mg/day for first week, which is increased to 15 mg/day on the second week and continue with the same dose until the end of the study along with their antipsychotic regimen for 12 weeks

Category

Treatment - Drugs

2**Description**

The control group receive their antipsychotic regimen with placebo for 12 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Zare hospital

Full name of responsible person

Narjes Hendouei

Street address**City**

Sari

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Moallem street-Moallem square-Vice chancellor for research Sari

City

Sari

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

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Assistant professor

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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