Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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 serotonine 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 ≥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

Dr Narjes Hendouei

Position

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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