

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluating the effect of aripiprazole as add on therapy for delirium prophylaxis in patients admitted to the intensive care unit

Protocol summary

Summary

This trial is to evaluate aripiprazole effect on prevention of delirium. This is a randomized, double blind, 2-armed parallel group clinical trial. Subjects are patients in in neurosurgical Intensive care unit in Firoozgar hospital, Tehran, Iran. Patients with active delirium, history of anti-psychotic therapy and bradycardia will be excluded. 40 patients will be enrolled. After randomization of the subject, 20 subjects in group A will receive aripiprazole 15mg daily by oral rout and 20 subjects in group B will receive placebo. The Confusion Assessment Method for the ICU will be used as validation tool for measurement of delirium daily. Finally the trend of The Confusion Assessment Method for the ICU will be compared between two groups. The primary objectives of this trial is to compare the incidence of delirium between control and intervention group using The Confusion Assessment Method for the ICU.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011810178N12**
Registration date: **2017-03-06, 1395/12/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-06, 1395/12/16

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of aripiprazole as add on therapy for delirium prophylaxis in patients admitted to the intensive care unit

Public title

Effect of aripiprazole on prevention of delerium

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 18-80 yo patients admitted to intensive care unit Exclusion criteria: pregnancy; breastfeeding; preexisting active delirium; bradycardia (heart rate <60); alcohol intoxication; liver failure (Child Pough Score: sever); kidney failure(GFR<15); history of anti-psychotic drug(s); ICU stay less than 3 days

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

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 Shahid Beheshti University of
Medical Sciences

Street address

Velenjak Street, Shahid Chamran High Way

City

Tehran

Postal code

Approval date

2016-07-20, 1395/04/30

Ethics committee reference number

IR.SBMU.PHNM.1395.408

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium, not induced by alcohol and other psychoactive
substances

Primary outcomes

1

Description

Delirium incidence

Timepoint

Entrance to study, Daily for 7 days

Method of measurement

Evaluation of CAM-ICU score

Secondary outcomes

1

Description

Drug effect on Lipid profile

Timepoint

Day 0 and 7

Method of measurement

Blood sample

2

Description

Drug effect on blood sugar

Timepoint

Daily

Method of measurement

Blood sample

3

Description

Drug effect on liver function tests

Timepoint

Day 0 and 7

Method of measurement

Blood sample

4

Description

Drug effect on ICU stay

Timepoint

Daily

Method of measurement

Counting the Admission days

Intervention groups

1

Description

Intervention: Tablet aripiprazole 15 mg daily orally for
seven days

Category

Treatment - Drugs

2

Description

Control: Tablet placebo once daily for 7 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar General Hospital

Full name of responsible person

Maryam Farasatinasab

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Behafarin St., Karimkhan Zand St., Vali-e-asr Sq.

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

Shahid Beheshti University of Medical Science

Full name of responsible person

Tahereh Shams

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

Yes

Title of funding source

Shahid Beheshti 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**

Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences

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Web page address**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*