

# 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

Mohammad Sistanizad

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8820 0087

##### Email address

sistanizadm@sbmu.ac.ir

##### 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

**Street address**

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

**City**

Tehran

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

Shahid Beheshti University of Medical Science

**Full name of responsible person**

Tahereh Shams

**Street address**

Velenjak Street, Shahid Chamran Highway

**City**

Tehran

**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

**Full name of responsible person**

Mohammad Sistanizad

**Position**

Assistant Professor, Clinical Pharmacy Specialist

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

Department of Clinical Pharmacy, Faculty of Pharmacy, Niayesh Highway

**City**

Tehran

**Postal code****Phone**

+98 218800087

**Fax****Email**

sistanizadm@sbmu.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department of critical care, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Majid mokhtari

**Position**

Assistant Professor, Pulmonologist

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

Shahid Madani street, Imam Hussein hospital

**City**

Tehran

**Postal code****Phone**

+98 21 73430

**Fax****Email**

majidmokh@gmail.com

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

Shahid Beheshti university of medical science

**Full name of responsible person**

Mina Jafarpour

**Position**

Pharmacy student

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

Vali-e-asr St, Niayesh

**City**

Tehran

**Postal code****Phone**

+98 21 8820 0118

**Fax****Email**

mina.jafarpour2020@gmail.com

**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*