# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Nov 2026

## Comparing effect of Aripiprazole with Nortriptyline on severity of Irritable Bowel Syndrome (IBS)

## Protocol summary

**Summary**

We decide to compare the effects of Aripiprazole (antimania) with nortriptyline (antidepressant) on severity of IBS symptoms. This is a prospective randomized control trail study. Inclusion criteria in this study are all patients with diagnosis of IBS who come to Poursina Hakin Clinic in Isfahan city. Exclusion criteria are patients with concurrent chronic diseases and severe psychological disorders. In the first 6 months of 1396 solar Hegira (April to September 2017) 84 patients with IBS are diagnosed by gastroenterologist selected and after taking consent enrolled in the study. The patients are randomly divided to two equal groups: One group are treated with Aripiprazole and another with low dose Nortriptyline. The validated questionnaires are used for evaluating severity of IBS symptoms and diagnosis of bipolar disorder. The questionnaires are filled before initiating treatment and then monthly to 3 months and each time the patients are evaluated by psychologist and if necessary the drugs' doses increased. After collecting data the groups are compared regarding severity of IBS and frequency of bipolar disorder.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017012227682N1**
Registration date: **2017-03-22, 1396/01/02**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2017-03-22, 1396/01/02

**Registrant information**

**Name**

Hojjatolah Rahimi

**Name of organization / entity**

Poursina Hakim research center

**Country**

Iran (Islamic Republic of)

**Phone**

+98 31 3554 8152

**Email address**

h_rahimi@resident.mui.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Poursina Hakim Research Center

**Expected recruitment start date**

2017-04-04, 1396/01/15

**Expected recruitment end date**

2017-09-23, 1396/07/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing effect of Aripiprazole with Nortriptyline on severity of Irritable Bowel Syndrome (IBS)

**Public title**

Effects of Aripiprazole on Irritable Bowel Syndrome (IBS)

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: all patients with diagnosis of IBS who come to Poursina Hakim clinic in Isfahan city exclusion criteria: patients with concurrent chronic diseases, major depression and severe bipolar disease who need specific psychological treatments; patients who consume psychotropic drugs; noncooperation with executors

**Age**

From **15 years** old to **80 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **84**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Isfahan University of Medical Siences

**Street address**
deputy of research and technology, building number 4, central staff of university, Isfahan University of Medical Siences, Hezar Jerib S., Isfahan, Iran

**City**
Isfahan

**Postal code**
81745-319

**Approval date**
2017-01-08, 1395/10/19

**Ethics committee reference number**
IR.MUI.REC.1395.4.068

## Health conditions studied

**1**

**Description of health condition studied**
Irritable bowel syndrome

**ICD-10 code**
K58

**ICD-10 code description**
Irritable bowel syndrome

## Primary outcomes

**1**

**Description**
Severity of IBS symptoms

**Timepoint**
Before trial, then monthly to 3 monnths during trial

**Method of measurement**
Standard questionnaire

## Secondary outcomes

**1**

**Description**
Frequency of bipolar disorder

**Timepoint**
Before trial, then monthly to 3 monnths during trial

**Method of measurement**
Standard questionnaire

## Intervention groups

**1**

**Description**
Intervention group: Aripiprazole Tab. 5 mg, first one half tab. per day and in the next follow ups if necessary increasing the dose up to 10mg/d till 3 months

**Category**
Treatment - Drugs

**2**

**Description**
Control group: Nortriptyline tab. 10mg, first one tab. per day and in the next follow ups if necessary increasing the dose up to 50mg/d till 3 months

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Pourcina Hakim Clinic

**Full name of responsible person**
Hojjatolah Rahimi (gastroenterologist)

**Street address**
building number 27, western Sheikh Mofid S., Isfahan, Iran

**City**
Isfahan

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Poursina Hakim Clinic

**Full name of responsible person**
Mohammad Hasan Emami (head of center)

**Street address**
building number 27, western Sheikh Mofid S., Isfahan, Iran
**City**
Isfahan

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Poursina Hakim Clinic

**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**
Poursina Hakim Clinic
**Full name of responsible person**
Hojjatolah Rahimi
**Position**
gastroenterologist/Physician working in the clinic
**Other areas of specialty/work**
**Street address**
building number 27, western Sheikh Mofid S., Isfahan, Iran
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+98 31 3664 0212
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www.ihsorg.ir

## Person responsible for scientific inquiries

**Contact**

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**Web page address**
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## Person responsible for updating data

**Contact**

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Poursina Hakim Clinic
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**Web page address**
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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*