

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of allopurinol and placebo in reducing depressive symptoms in patients with major depressive disorder

#### Protocol summary

##### Summary

The aim of this study was to investigate the role of allopurinol in the treatment of major depression in a double-blinded, 70 patients with major depression referred to Amir Kabir Hospital after diagnosis according to the clinical interview based on DSMV-TR randomly divided into two equal groups Both groups received 40 mg of citalopram for 6 weeks in addition to the 300 mg allopurinol daily citalopram treatment group and the control group will receive a placebo. At the end of the third week and sixth of the Hamilton depression will be reassessed. Also, the effects of allopurinol liver after 2 to 4 weeks of treatment, liver tests will be repeated again. Inclusion criteria: age 18 to 65 years, diagnosed with major depression based on clinical interviews and diagnostic criteria for DSM V; normal blood levels of uric acid and liver enzymes (ALT, AST) Exclusion criteria: Serious psychiatric disorders, personality disorders; Taking several drugs simultaneously; severe physical illness; Sensitivity to allopurinol

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201508277373N6**

Registration date: **2015-12-03, 1394/09/12**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-12-03, 1394/09/12

##### Registrant information

###### Name

Hamidreza Jamilian

###### Name of organization / entity

Arak University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 1222 5758

###### Email address

jamilian.hr@arakmu.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Deputy for Research and Technology Arak University of Medical Sciences

###### Expected recruitment start date

2015-07-11, 1394/04/20

###### Expected recruitment end date

2016-07-10, 1395/04/20

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparison of the effectiveness of allopurinol and placebo in reducing depressive symptoms in patients with major depressive disorder

###### Public title

Comparison of the effectiveness of allopurinol and placebo in reducing depressive symptoms in patients with major depressive disorder

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: age 18 to 65 years, diagnosed with major depression based on clinical interviews and diagnostic criteria for DSM V; normal blood levels of uric acid and liver enzymes (ALT, AST) Exclusion criteria: Serious psychiatric disorders, personality disorders;

Taking several drugs simultaneously; severe physical illness; Sensitivity to allopurinol

### Age

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

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **70**

### Randomization (investigator's opinion)

N/A

### 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

Arak University of Medical Sciences

##### Street address

Alamolhoda St., Maskan St., Arak

##### City

Arak

##### Postal code

#### Approval date

2015-07-11, 1394/04/20

#### Ethics committee reference number

IR.ARAKMU.REC.1394.68

## Health conditions studied

### 1

#### Description of health condition studied

Major depression

#### ICD-10 code

F32.0

#### ICD-10 code description

Mild depressive episode

### 2

#### Description of health condition studied

Major depression

#### ICD-10 code

F32.1

### ICD-10 code description

Moderate depressive episode

## Primary outcomes

### 1

#### Description

Hamilton Square

#### Timepoint

Before the intervention, 4 to 6 weeks, end of study

#### Method of measurement

Hamilton questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The intervention group clinical citalopram 40 mg for 6 weeks plus allopurinol 300 mg daily receive.

#### Category

Treatment - Drugs

### 2

#### Description

Clinical citalopram 40 mg daily for 6 weeks plus a control group that received placebo.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir Kabir Hospital and Emam Reza Clinical

##### Full name of responsible person

Dr. Jamilian Hamidreza

##### Street address

Amir Kabir Hospital, Rahahan St., Arak

##### City

Arak

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr. Rafiee Mohammad

##### Street address

School of Medicine, Alamolhoda St., Maskan St., Arak

##### City

Arak

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Arak 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**

Arak University of Medical Sciences

**Full name of responsible person**

Dr. Ranjbaran Farideh

**Position**

Resident of Psychiatry

**Other areas of specialty/work**

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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*