

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### The efficacy of pramipexole as an adjuvant treatment with citalopram for treating major depressive disorder, a randomized placebo controlled clinical trial

#### Protocol summary

##### Summary

This 6-week randomized controlled clinical trial examines the adjuvant effect of pramipexole (0.18 mg/day) to citalopram (20mg/day) for treating adult patients aged between 18 to 65 years old diagnosed with major depressive disorder. Hamilton depression rating scale is used to assess the severity of depression. The patients are evaluated at baseline, week 2, week 4, and week 8.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201312263930N30**  
Registration date: **2014-11-27, 1393/09/06**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-11-27, 1393/09/06

##### Registrant information

###### Name

Ahmad Ghanizadeh

###### Name of organization / entity

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1627 3070

###### Email address

ghanizad@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2013-10-07, 1392/07/15

##### Expected recruitment end date

2015-06-07, 1394/03/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The efficacy of pramipexole as an adjuvant treatment with citalopram for treating major depressive disorder, a randomized placebo controlled clinical trial

##### Public title

The efficacy of pramipexole as an adjuvant treatment with citalopram for treating major depressive disorder

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: patients aged 18 to 65 years old, major depressive disorder using DSM-IV diagnostic criteria.

Exclusion criteria: serious uncontrolled medical conditions, bipolar mood disorder.

##### Age

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

##### Gender

Both

##### Phase

2

##### 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

Shiraz University of Medical Sciences

##### Street address

Shiraz University of Medical Sciences

##### City

Shiraz

##### Postal code

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#### Approval date

2013-10-06, 1392/07/14

#### Ethics committee reference number

Ct-92-6141

## Health conditions studied

### 1

#### Description of health condition studied

Major depressive disorder

#### ICD-10 code

F32

#### ICD-10 code description

Depressive episode

## Primary outcomes

### 1

#### Description

Depression

#### Timepoint

baseline, week 2, week 4, and week 6

#### Method of measurement

Hamilton Derepression Rating Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Citalopram (20mg/day) plus pramipexole (0.180mg/day)

#### Category

Treatment - Drugs

### 2

#### Description

Citalopram (20mg/day) plus placebo

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Research Center for Psychiatry and Behavioral Sciences, Shiraz University of Medical Sciences

##### Full name of responsible person

##### Street address

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical sciences

##### Full name of responsible person

Basir Hashemi

##### Street address

Vice-chancellery of Research Affairs, Shiraz University of Medical sciences, Zand Street

##### City

Shiraz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shiraz 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**

Shiraz University of Medical sciences

**Full name of responsible person**

Ahmad Ghanizadeh

**Position**

Professor of Psychiatry

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

Hafez Hospital

**City**

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**Fax****Email**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Research Center for Psychiatry and Behavioral Sciences, Shiraz University Of Medical Sciences

**Full name of responsible person**

Ahmad Ghanizadeh

**Position**

Professor of Psychiatry

## Other areas of specialty/work

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**Web page address**

## Person responsible for updating data

### Contact

## 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*