Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

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

Public title

The efficacy of pramipixole 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 Sceinces
Street address
Shiraz University of Medical Sceinces
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 Derepssion 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
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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