Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Citalopram and Pramipexole treatments on depression in Parkinson disease

Protocol summary

Study aim
Comparison of Citalopram and Pramipexole treatments on depression in Parkinson disease

Design
Two arm parallel groups trial randomised simply by using random number table

Settings and conduct
This study is performed on patients referred to neurology clinic of Alzahra and Khorshid hospitals in Isfahan. During the study, patients will be assessed for depression using Beck Depression Inventory and Quality of Life Assessment with Parkinson's Disease Questionnaire at baseline and after 8 weeks of treatment with citalopram or pramipexole.

Participants/Inclusion and exclusion criteria
Patients were included if they were between the ages of 35 and 80, had a confirmed diagnosis of Parkinson disease and had a diagnosis for the Diagnostic and Statistical Manual of Mental Disorders 5th ed. (DSM-V) of Depressive disorders. Patients were excluded if they had cognitive impairment (Mini-Mental State Examination [MMSE] less than 27), had a psychotic disorder and suicidal thought or attempt, use of antipsychotics, anticholinergics, dopamine agonists and other psychological therapies, use of metoclopramide, methyldopa, methylphenidate, reserpine, flunarizine, cinnarizine, or amphetamine derivatives within the past 3 months, a history of malignant melanoma; or previous deep brain stimulation surgery, pregnant or lactating women, use of contraception and were “off” for greater than 50% of the day.

Intervention groups
Patients were randomly assigned to pramipexole or citalopram.

Main outcome variables
Compare change in Beck Depression Inventory total score and quality of life (PDQ-39 total score) baseline and after treatment in two groups (citalopram and pramipxole)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191111045407N1**
Registration date: **2019-12-13, 1398/09/22**
Registration timing: **prospective**

Last update: **2019-12-13, 1398/09/22**
Update count: **0**

Registration date
2019-12-13, 1398/09/22

Registrant information

Name
Ehsan Ziaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3628 6302

Email address
ziaei@resident.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of Citalopram and Pramipexole treatments on depression in Parkinson disease

Public title
Citalopram and Pramipexole in depression in Parkinson disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Controlled disease with monotheraphy with Levodopa
Exclusion criteria:
Cognitive disorders Psychotic disorders and suicidal thought or attempt Use of antipsychotics, anticholinergics, dopamine agonists and other psychological drugs and therapies Use of metoclopramide, methyldopa, methylphenidate, reserpine, flunarizine, Cinnarizine and amphetamine derivatives within the past 3 months History of malignant melanoma History of previous deep brain stimulation surgery Pregnancy Lactating using contraceptive drugs “Off” period for greater than 50% of the day
Age
From **35 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple Random Samples From a Table of Random Numbers
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
Ethics committee of Isfahan University of Medical Sciences
Street address
No. 160, Tayebantayeba alley, Shahidi Alley, Khaghani St.
City
Isfahan
Province
Isfehan
Postal code
8175844511
Approval date
2019-11-02, 1398/08/11
Ethics committee reference number
IR.MUI.MED.REC.1398.403

Health conditions studied

1

Description of health condition studied
Parkinson disease
ICD-10 code
G20
ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
Beck depression inventory total score
Timepoint
Assessment of depression score in Beck depression inventory at baseline (before intervention) and 8 weeks after starting pramipexole or citalopram
Method of measurement
Beck depression inventory

Secondary outcomes

1

Description
Quality of life score
Timepoint
Assessment of quality of life score with Parkinson's Disease Questionnaire at baseline (before intervention) and 8 weeks after starting pramipexole or citalopram
Method of measurement
Parkinson's Disease Questionnaire

Intervention groups

1

Description
Intervention group 1: Patients receiving citalopram 10 mg daily for the first week and then 20 mg daily
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients receiving pramipexole

0.09 mg twice a day for the first week and then 0.18 mg twice a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Ahmad Chitsaz

Street address

Shohadaye Sofe Blvd

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Isfahan

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8174675731

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2

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

Parisa Emami

Street address

Ostandari St, Hashbehesht Blvd

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8145831451

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Hezarjarib St

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8174673461

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research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ehsan Ziaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available