

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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, methyl dopa, 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 pramipexole)

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 monotherapy 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, methylodopa, 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

Isfahan

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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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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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 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