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, methylidopa, 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

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Iran (Islamic Republic of)
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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, methylclopra, 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
City
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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
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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
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Position
Resident
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Other areas of specialty/work
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**Person responsible for updating data**

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**Position**
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**Latest degree**
Medical doctor

**Other areas of specialty/work**
Neurology

**Street address**
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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