

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the effect of Bupropion with sertraline on the treatment of depression in Parkinson patients.

Protocol summary

Study aim

Comparison of the effect of Bupropion with sertraline on the treatment of depression in Parkinson patients.

Design

Two-way blind clinical trial, with two parallel groups, randomized in 42 patients

Settings and conduct

The study is being conducted at Roozbeh Psychiatric Hospital. Depressed Parkinson's patients are randomly divided into two groups. One group will receive bupropion and the second group will receive sertraline. Drugs will be given to patients in envelopes without medication information, and the primary outcome assessor is not aware of patient grouping, so the study will be double-blind.

Participants/Inclusion and exclusion criteria

Criteria for entry into the study: Parkinson's patients with depression. Criteria for not entering the study: history of other major neurological disorders such as epilepsy, history of head trauma, vascular disorders, stroke and dementia and history of other major psychiatric disorders including bipolar disorder, schizophrenia, substance abuse and history of antipsychotic drugs. One last year.

Intervention groups

There are two intervention groups in this study:
Intervention group 1: Bupropion with an initial dose of 75 mg daily and if there is no initial response after one month, the dose will be increased to 150 mg daily.
Intervention Group 2: Sertraline with a daily dose of 50 mg and if there is no initial response after one month, the dose will be increased to 100 mg daily.

Main outcome variables

depression severity; Parkinson severity; duration of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200513047429N1**

Registration date: **2020-06-28, 1399/04/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-28, 1399/04/08**

Update count: **0**

Registration date

2020-06-28, 1399/04/08

Registrant information

Name

Ashraf Fayazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8896 3223

Email address

fayaziyalda@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-09, 1399/03/20

Expected recruitment end date

2020-12-10, 1399/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Bupropion with sertraline on the treatment of depression in Parkinson patients.

Public title

Comparison Bupropion with srtraline on the depression in Parkinson

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Parkinson's patients with major depression,

Exclusion criteria:

Absence history of other major neurological disorders, such as epilepsy, head trauma, vascular disorders, stroke and dementia, and other major psychiatric disorders, including bipolar disorder, schizophrenia, substance abuse, and use of Antipsychotics in the last 6 months

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Our study is a randomized double-blind trial. Both patients and assessors will be unaware of the type of intervention for each patient. For randomization, we will use the simple randomization method, and for this purpose, Random number table will be used. First, the researcher predetermines the table to read the numbers (eg, top, bottom, left, or right), and the researcher also specifies how the numbers will be assigned to the two intervention groups ((For example, odd numbers for the Bupropion group and even numbers for the sertraline group). The researcher then touches one of the numbers and moves in one of the predefined directions, recording the numbers and assigning them to different groups. A nurse who is not involved in the intervention and delivery of the results, and delivers the medicine to the patient based on the patient's membership.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medications are given to a patient in a packet without medication information. Any subsequent follow-up of the patient will be performed by a physician who is unaware of the patient's membership.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical sciences

Street address

No. 2 East Sahand Alley., Babataher Ave., Fatemi Ave.,

City

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Province

Tehran

Postal code

1414655541

Approval date

2020-04-28, 1399/02/09

Ethics committee reference number

IR.TUMS.VCR.REC.1399.297

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

2

Description of health condition studied

Parkinson

ICD-10 code

G20

ICD-10 code description

Parkinson's disease

Primary outcomes

1

Description

Severity of depression based on Beck's questionnaire

Timepoint

Measuring depression before intervention and then 1 and 3 month after intervention

Method of measurement

Beck's depression questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Depressed Parkinson's patients will be prescribed Bupropion tablets at an initial dose of 75 mg daily, and if there is no initial response after one month, the dose will be increased to 150 mg daily. The above drug is manufactured by Abidi Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Intervention group: Depressed patients with Parkinson's disease, Sertraline at a dose of 50 mg daily, and if there is no initial response after one month, an increase in dose to 100 mg daily will be prescribed. It is an drug from Abidi Pharmaceutical Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Fayazi Ashraf

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south Kargar Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Keshavarz Boulevard, corner of Quds Street, Central University Organization, sixth floor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fayazi Ashraf

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Ashraf Fayazi

Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ashraf Fayazi

Position

Resident

Latest degree

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Other areas of specialty/work

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