

# 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**

Tehran

##### **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

**Street address**

south Kargar Ave.

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hosp\_roozbeh@tums.ac.ir

**Web page address**

<http://roozbehhospital.tums.ac.ir>

## 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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**Province**

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1417653911

**Phone**

+98 21 8163 3686

**Email**

vcr@tums.ac.ir

**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

#### Contact

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**Position**

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**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**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**