Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of therapeutic effects of modafinil plus sertraline versus sertraline plus placebo in outpatient treatment of major depressive disorder: a clinical trial

Protocol summary

Study aim
Comparison of the effects of Modafinil plus Sertralin and Sertralin plus placebo in treatment of major depressive disorder

Design
Triple blind clinical trial consisting of case and control groups; third phase on 50 patients.

Settings and conduct
We did sampling during 6 months at Imam Hossein hospital, Karaj. Telephone follow-up was done 6 weeks after initiation of treatment. In this study; patients, physician and analysor will be kept blind. Using placebo similar in shape to Modafinil for patients and specific codes for analysor and physician, they will be kept blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of Major depressive disorder; Obtaining informed consent. Non-inclusion criteria: Diagnosis of bipolar mood disorder, ADHD or any underlying medical disease; use of any illicit drugs; past history of suicide

Intervention groups
Intervention group: receiving 200 mg of Modafinil each 12 hours plus standard dose of Sertraline for 6 weeks. Control group: receiving placebo plus standard dose of Sertraline for 6 weeks

Main outcome variables
Fatigue severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180522039784N1**
Registration date: **2020-08-09, 1399/05/19**
Registration timing: **retrospective**
Last update: **2020-08-09, 1399/05/19**
Update count: **0**

Registration date
2020-08-09, 1399/05/19

Registrant information

Name
Pouria Chaghamirzayi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3450 2485

Email address
pouriachaghamirzayi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2020-02-19, 1398/11/30

Actual recruitment start date
2019-09-23, 1398/07/01

Actual recruitment end date
2020-02-18, 1398/11/29

Trial completion date
2020-04-19, 1399/01/31

Scientific title
Comparison of therapeutic effects of modafinil plus sertraline versus sertraline plus placebo in outpatient treatment of major depressive disorder: a clinical trial

Public title
Evaluation of the effect of Modafinil in the treatment of major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of major depressive disorder Informed consent

Exclusion criteria:

Diagnosis of bipolar mood disorder, ADHD or any underlying medical disease Use of any illicit drugs Use of any medication that interferes modafinil action Past history of suicide Past history of receiving ECT Pregnancy Daily use of more than 250 mg of caffeine

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the number of clinic's receipt (being even or odds) patients will be divided in two groups. Patients with even turns will be allocated to control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

We will give each patient a specific code, which neither physician or analysor won't know that which code belongs to which group. Using placebo similar in shape to modafinil, patients won't informed their group. After analysis, research's manager will replace codes with actual groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Alborz University of Medical Sciences

Street address

Imam hussain hospital; Mahdasht road

City

karaj

Province

Alborz

Postal code

1631735361

Approval date

2019-09-22, 1398/06/31

Ethics committee reference number

IR.ABZUMS.REC.1399.095

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Fatigue severity

Timepoint

Before intervention and 6 weeks after initiation

Method of measurement

Fatigue severity scale

2

Description

Mood cahnges

Timepoint

Before intervention and 6 weeks after initiation

Method of measurement

Beck's depression inventory

Secondary outcomes

1

Description

Drug side effects

Timepoint

Six weeks after intervention

Method of measurement

Obtaining history

Intervention groups

1

Description

Intervention group: receiving 200 mg of Modafinil each 12 hours plus standard dose of Sertraline for 6 weeks.

Category

Treatment - Drugs

2

Description
Control group: receiving placebo every 12 hours plus standard dose of Sertraline for 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatry clinic of Imam Hussain Hospital
Full name of responsible person
Dr. Marzie Assare
Street address
Mahdasht road
City
karaj
Province
Alborz
Postal code
1631735361
Phone
+98 26 3622 0118
Email
emamhosseinhp.karaj@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Dr. Reza Bayrami
Street address
Nabovvat Blvd
City
Karaj
Province
Alborz
Postal code
1631735361
Phone
+98 26 3255 5000
Email
abzumc.ac.ir@gmial.com
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj University of Medical Sciences
Proportion provided by this source
20
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
Karaj University of Medical Sciences
Full name of responsible person
Hamed Shabani
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Medical Education
Street address
Dabestan street; Seyedkhandan
City
Tehran
Province
Alborz
Postal code
1631735361
Phone
+98 21 8846 7286
Email
Pacino1373@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Dr. Marzie Assare
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Psychiatrics
Street address
Alborz University of Medical Sciences; Nabovvat blvd
City
Karaj
Province
Alborz
Postal code
1631735361
Phone
+98 21 8846 7286
Email
hhsgdn@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Pouria Mirzayi

Position
Consultant

Latest degree
Medical doctor

Other areas of specialty/work
Epidemiology

Street address
Golshahr avenue

City
Karaj

Province
Alborz

Postal code
1631735361

Phone
+98 902 890 2005

Email
Pouriachaghamirzayi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
I will be willing to share this information with researchers who are conducting larger studies.I will give data to vice chancellor for research

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