

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 analyzor will be kept blind. Using placebo similar in shape to Modafinil for patients and specific codes for analyzor 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

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Phone

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Email

abzumc.ac.ir@gmail.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

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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

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Alborz University of Medical Sciences; Nabovvat blvd

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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

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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