Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Investigation of the efficacy of Modafinil augmentation of antidepressant treatment on working memory in patients with major depressive disorder: A randomized double-blind clinical trial

Protocol summary

Study aim
The main aim of this study is to evaluate the efficacy of Modafinil augmentation of antidepressant treatment on working memory in patients with major depressive disorder through a double-blind randomized, placebo-controlled clinical trial.

Design
Double-blind randomized, placebo-controlled clinical trial with 90 participants

Settings and conduct
Outpatient clinic of Ebn'e Sina hospital and psychiatric offices in Mashhad. Blinding of participants,researchers and evaluators.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Confirmed history of major depressive disorder based on the DSM-5 criteria, now in the recovery phase and receiving SSRIs or SNRIs; 2- Beck Depression Inventory score less than 28; 3- 18 to 40 years old; 4-The patient has not had more than three episodes; 5- Mean score of 30 for positive affect and 15 for negative; affect on Positive and Negative Affect Schedule (PANAS); 6- Completing the informed consent form. Exclusion criteria: 1- Suffering any other major psychiatric illnesses; 2- Thyroid, immunological or neurological problems and other contraindications to Modafinil (such as refractory hypertension or history of cardiac arrhythmia) based on clinical history; 4- Mental retardation; 5- History of head injury or substance abuse;

Intervention groups
The intervention group receive Modafinil for eight weeks in addition to standard antidepressant medication with SSRIs or SNRIs. The drug is initially administered for one week at dose of 100 mg/day and then continued at dose of 200 mg/day. The control group receive standard antidepressant medication and placebo for eight weeks according to the protocol. At weeks 0, 2, 4, and 8, working memory in participants whose Positive and Negative Affect Schedule (PANAS) scores is within normal range is assessed by word/non word span test.

Main outcome variables
Working memory

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091019002611N4**
Registration date: **2019-10-02, 1398/07/10**
Registration timing: **prospective**

Last update: **2019-10-02, 1398/07/10**
Update count: **0**

Registration date
2019-10-02, 1398/07/10

Registrant information

Name
Mohammad Reza Fayyazi Bordbar

Name of organization / entity
Psychiatry and Bahavioral Sciences Research Center, Psychiatry group, Mashhad University of Medical

Country
Iran (Islamic Republic of)

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fayyazimr@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-22, 1398/07/30

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the efficacy of Modafinil augmentation of antidepressant treatment on working memory in patients with major depressive disorder: A randomized double-blind clinical trial

Public title

The efficacy of Modafinil on working memory in patients with major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed history of major depressive disorder based on the DSM-5 criteria, now in the recovery phase and receiving SSRIs or SNRIs Beck Depression Inventory score less than 28 18 to 40 years old The patient has not had more than three episodes Mean score of 30 for positive affect and 15 for negative affect on Positive and Negative Affect Schedule (PANAS) test Completing the informed consent form

Exclusion criteria:

Suffering any other major psychiatric illnesses Thyroid, immunological or neurological problems and other contraindications to Modafinil (such as refractory hypertension or history of cardiac arrhythmia) based on clinical history Mental retardation History of head injury or substance abuse

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized block design, table of random numbers, sealed envelopes

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are unaware of the target group (intervention or control), researchers and evaluators are unaware of each participant dedicated group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad university of medical sciences, Daneshgah ST., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

91357-345

Approval date

2019-03-12, 1397/12/21

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.274

Health conditions studied

1

Description of health condition studied

Major depressive disorder

ICD-10 code

F33.0

ICD-10 code description

Major depressive disorder, recurrent, mild

Primary outcomes

1

Description

Working memory capacity, measured by Persian word/non word span test

Timepoint

weeks 0, 2, 4 & 8 of drug administration

Method of measurement

Persian word/non word span test

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group receive Modafinil for eight weeks in addition to standard antidepressant medication with SSRIs or SNRIs. The drug is initially administered for one week at dose of 100 mg/day and then continued at dose of 200 mg/day.

Category

Treatment - Drugs

2

Description

Control group: the intervention group receive placebo for eight weeks in addition to standard antidepressant medication with SSRIs or SNRIs.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient private and public psychiatric clinics in Mashhad

Full name of responsible person

Mohammad Reza Fayyazi Bordbar

Street address

Ebn'e Sina hospital, Horr Ameli Blvd., Mashhad, Iran

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fayyazimr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Web page address

http://v-research.mums.ac.ir/index.php/moaven/tafaghodim

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Reza Fayyazi Bordbar

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Main outcome information;
When the data will become available and for how long
Six month after publishing the results;
To whom data/document is available
Researchers working in academic and scientific institutions;
Under which criteria data/document could be used
Requesting the opinion of the project manager before performing any analysis;
From where data/document is obtainable
Dr.Mohammad Reza Fayyazi Bordbar
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What processes are involved for a request to access data/document
Submit request via email, receiving response from project manager;
Comments