

# 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 Behavioral Sciences Research Center, Psychiatry group, Mashhad University of Medical

##### Country

Iran (Islamic Republic of)

##### Phone

00985117112721 , 00985117002306

##### Email address

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

**City**

Mashhad

**Province**

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**Postal code**

9195983134

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+98 51 3711 2701

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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

**Street address**

Mashhad University of medical sciences, Daneshgah St., Mashhad, Iran

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+98 51 3882 3255

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+98 51 3882 3251

**Email**

tafaghodim@mums.ac.ir

**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

**Street address**

Jbn-e-Sina hospital, Hor-e-Ameli Blvd., Mashhad, Iran

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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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  
fayyazimr@mums.ac.ir

**What processes are involved for a request to access data/document**

Submit request via email, receiving response from project manager;

**Comments**