Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of The Effect of Modafinil and Citalopram On The Treatment of Major Depression

Protocol summary

Study aim
Comparison of The Effect of Modafinil and Citalopram On The Treatment of Major Depression

Design
Clinical trial with control group, with parallel groups, three-way blind, randomized, phase 3 on 30 patients. Block randomization

Settings and conduct
Therapeutic intervention on clients of the psychiatric clinic of Golestan Hospital in Ahvaz in a three-way blind (project facilitator, patient and project consultant) by similar and pre-determined drug packages by the study supervisor

Participants/Inclusion and exclusion criteria
Entering criteria: 1. Age between 18-65 years. 2. Initial clinical diagnosis of major depressive disorder. 3.Written consent to enter the study from the patient or his / her guardian. 4.Ability to take medicine. 5. Hamilton Depression Score above 25. Exclusion criteria: 1. Depression caused by a physical illness or the use of drugs and substances 2. Existence of any severe and chronic physical illness 3. History of gastric ulcer 4. Pregnancy 5. History of alcohol and substance abuse during the 6 months before the start of the project 6. History of manic episodes 7.Intellectual disorders 8. Psychosis 9. Breastfeeding 10. High severity of depression 11. History of receiving antidepressant in two to four weeks before starting the drug 12.History of no Responding or having shifts with the studied drugs 13. History of receiving lithium, lamotrigine, sodium valproate, atypical antipsychotics available other than ziprasidone and aripiprazole, in the past two weeks or one month 14. Being treated with Ritalin 15. Existence of mixed symptoms in the recent episode 16. Existence of anxiety disorder

Intervention groups
The intervention group receives modafinil 200 mg every morning and evaluates in 3rd and 6th week after start. The control group receives citalopram 40 mg daily and evaluates in 3rd and 6th week after start.

Main outcome variables
The treatment of major depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201026049152N1**
Registration date: **2020-11-28, 1399/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-28, 1399/09/08**
Update count: **0**

Registration date
2020-11-28, 1399/09/08

Registrant information

Name
Golsa Safaei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-21, 1399/09/01

Expected recruitment end date
2021-07-23, 1400/05/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The Effect of Modafinil and Citalopram On The Treatment of Major Depression

Public title

Comparison of The Effect of Modafinil and Citalopram On The Treatment of Major Depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 65 years Diagnosis of clinical Major Depressive Disorder based on the DSM5 criteria A score above 25 on the Hamilton Depression Rating Scale Written consent to enter the study from the patient or her /his guardian The patient is able to take medicine

Exclusion criteria:

Depression caused by physical illness or the use of drugs and substances Existence of any severe and chronic physical illness (brain, cardiovascular disease, seizure or history of substance abuse) History of gastric ulcer Pregnancy History of alcohol use and substance abuse during the 6 months prior to the start of the project History of manic episodes Intellectual disorders Psychosis Breastfeeding High severity of depression such as melancholic and suicidal ideation History of receiving antidepressant in two to four weeks before starting the drug (eg MAOIs in the last four weeks but SSRIs or mirtazapine or SNRIs in the last two weeks) History of non-response or shifting with the studied drugs History of receiving lithium, lamotrigine, sodium valproate, atypical antipsychotics available other than ziprasidone and aripiprazole, in the past two weeks or one month (depending on the half-life of the drug or based on similar studies) Being treated with Ritalin for any reason Existence of mixed symptoms in the recent episode Existence of anxiety disorder, especially panic

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization method is used. The main idea of block randomization is to divide patients into M blocks of size 2N, so that in each block N patients are assigned A and patients N are assigned to B. The block is then randomly selected. This method ensures equal treatment allocation per block provided the block is fully utilized. The size of the block, depending on the number of treatments, should be short enough to prevent imbalance, and large enough to prevent guessing treatment allocation in each group during the study. The block size should be at least twice the number of treatment nodes. The size of the block is not stated in the study so that researchers are blind to it. If the blocks are expressed, the treatment series in each block can be guessed. This can lead to selection bias. The solution to prevent this error is to: (1) Lack of disclosure of block mechanism (2) Use of random block size In both groups, the drugs will be given to the patients in the same way and they will receive the medicine on the same days and in the same way. Everyone on the research team, like patients and their families, will be unaware of the treatment groups designed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients are treated with medication packages pre-determined by the study supervisor (supervisor Professor) Drug packages are completely similar in shape and the patient and the project manager are not aware of the contents of the packages. In addition, collecting information, assessing patients and completing the forms is done by the project manager and his assistant who are not aware of the contents of the packages. ; In the data analysis stage, the analysis will be performed by the project consultant and the project manager who are not aware of the contents of the drug packages and only the group of patients (group 1 or 2) will be identified for data analysis; Therefore, the study is three way blind and the contents of the two drug groups are not clear from the stage of the patient entering the study to conduct the study, data collection and analysis of information.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Jondishapur University of Medical Sciences

Street address

Ethics Committee Center,Golestan Hospital,Golestan Blvd

City

Ahvaz

Province

Khouzestan

Postal code
6136835685
Approval date
2020-02-01, 1398/11/12
Ethics committee reference number
IR.AJUMS.REC.1398.830

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
Depression score on the Hamilton questionnaire
Timepoint
At the beginning of the study and three weeks and six weeks after the start of the intervention
Method of measurement
The Hamilton questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group receives 200 mg of modafinil (2 of 100 mg tablets made in Iran) every morning and will be re-evaluated by Hamilton Depression Inventory three weeks and six weeks after the start of the intervention.
Category
Treatment - Drugs

2

Description
Control group: This group receives two 20 mg citalopram tablets made in Iran, which have been standardized with modafinil, equivalent to 40 mg citalopram every day, and will be re-evaluated by Hamilton questionnaire three weeks and six weeks after the start of the intervention.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Psychiatric Clinic of Golestan Hospital
Full name of responsible person
Hamzeh Rostami
Street address
Psychiatry department,Golestan hospital,Golestan boulvard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Ahvaz Jundishapour University of Medical Sciences, Golestan Blv, Ahvaz, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Golsa Safaei

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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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