

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

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 6894

Email address

golsa.safaei@gmail.com

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

Khuzestan

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 boulevard

City

Ahvaz

Province

Khuzestan

Postal code

6136835685

Phone

+98 61 3374 3001

Email

Golsa.safaei@gmail.com

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

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Phone

+98 61 3587 4366

Email

src@ajums.ac.ir

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

Golsa.safaei@gmail.com

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

Street address

No 14, Maryam Alley, East Soroush St, East Kianpars St

City

Ahvaz

Province

Khouzestan

Postal code

6155686395

Phone

+98 61 3333 6894

Email

Golsa.safaei@gmail.com

Person responsible for scientific 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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Khouzestan

Postal code

6155686395

Phone

+98 61 3333 6894

Email

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Golsa Safaei

Position

Resident

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+98 61 3333 6894

Email

Golsa.safaei@gmail.com

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