

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

The effect of Modafinil and placebo on improving consciousness in patients with COVID-19 with loss of consciousness

Protocol summary

Study aim

Determining the effect of prescribing Modafinil on improving consciousness in patients with COVID-19 with loss of consciousness.

Design

The design of this study was a parallel. In terms of blinding, it is double blinded, which will be performed on 60 patients. For randomization was used of blocked method for patients in the drug group or placebo, based on the number assigned to patients. Medications (or placebo) for each patient were identified by a number on the box, which is the patient code, and are delivered to the nurse by the researcher.

Settings and conduct

Study will perform on COVID-19 patients in Rasoul Akram Hospital. After obtaining consent from patients or relatives and performing randomization, patients will be assigned into Modafinil and placebo arms. 30 patients are admitted in each arm. The third physician, who only has access to patient numbers, will measure the level of consciousness. Modafinil was administered orally or by gavage at a dose of 100 mg at 8 am and every two hours is administered 100 mg to reach a total dose of 400 mg. Consciousness (initial outcome) was assessed and in case of significant improvement in the level of consciousness according to the standard (GCS) measured by physician, drug should be continued at a dose of 400 mg daily for two weeks and if there is no change in consciousness according to the GCS standard Will be cut off. In the placebo group, patients will given oral placebo with a similar manner.

Participants/Inclusion and exclusion criteria

COVID-19 patients with declining in the level of consciousness. Patients with adverse reaction to Modafinil and those with a history of seizure would remove from the study.

Intervention groups

Patients with COVID-19 will be assigned into two groups Modafinil and placebo receiving with decreased level of

consciousness.

Main outcome variables

Level of consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170903036041N3**

Registration date: **2021-05-23, 1400/03/02**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-23, 1400/03/02**

Update count: **0**

Registration date

2021-05-23, 1400/03/02

Registrant information

Name

Omid Moradi Moghadam

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6653 9233

Email address

moradimoghadam.o@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Modafinil and placebo on improving consciousness in patients with COVID-19 with loss of consciousness

Public title

The effect of Modafinil on improving consciousness with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Confirm patient with clinical feature, laboratory and chest CT scan Having mild decrease level of consciousness, drowsiness to deep coma

Exclusion criteria:

History of seizure Clinical feature accompanied after drug consumption Drug side effects

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process in this study is using by Random Allocation software. Which first defines the number of groups to the software and then determines the type of randomization. The randomization method is considered to be block type. In this method, in addition to reducing the differences between groups in terms of sample size, minimize the applying of researchers' opinions in assigning patients to study groups. Definition and output of randomization software is performed by the epidemiologist and the project manager knows the type of study groups and interventions. Each patient will be assigned a number taken from the Random Allocation software and each patient selected based on inclusion and non-inclusion criteria for the study will be notified to the project manager and he will announce the type of intervention based on patient Selected to study and match that number with the software output. Drug and placebo have the same shape and only the patient number will be written on it. Only the project manager will know the order of receiving the interventions as well as the type of interventions.

Blinding (investigator's opinion)

Double blinded

Blinding description

According to the randomization method, except the principle investigator, no other person is aware whether the patient is in the drug or placebo group. The participants and outcome assessor will be blinded regarding the patient's position in either trial groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran university of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-12-26, 1399/10/06

Ethics committee reference number

IR.IUMS.REC.1399.1056

Health conditions studied**1****Description of health condition studied**

Coronavirus 2019

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes**1****Description**

Level of consciousness

Timepoint

On admission and after 3 days

Method of measurement

Glasgow Coma Scale

2**Description**

Headache

Timepoint

On admission and after 3 days

Method of measurement

Interview with the patient

3**Description**

Seizure

Timepoint

On admission and after 3 days

Method of measurement

Observation, examination and recording data

Secondary outcomes**1****Description**

Biochemical laboratory data

Timepoint

Before intervention and daily in duration of intervention

Method of measurement

Laboratory kit

Intervention groups**1****Description**

Intervention group: Modafinil (100 mg Tablets) is administered orally or by gavage at the rate of 100 mg every 8 hours and in case of no complications or changes in hemodynamics, 100 mg every two hours is re-prescribed up to 400 mg, reach the total dose (plasma peak of the drug is 2-4 hours). Two hours after each dose and before the next dose and two hours after the last dose (10, 12, 14 and 16 hours) consciousness (initial outcome) was assessed and in case of significant improvement in the level of consciousness according to Glasgow criteria coma scale (GCS) The drug is continued for up to two weeks at a dose of 400 mg daily and will be discontinued if there is no change in consciousness according to the GCS standard. In addition, all treatment measures will be conducted according to the national therapeutic protocol for the patients.

Category

Treatment - Drugs

2**Description**

Control group: In this group, placebo will be prescribe to the patients which have no therapeutic effect and are similar in color and shape to Medafinil tablets.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasoul Akram hospital

Full name of responsible person

Omid Moradimoghadam

Street address

Rasoul Akram hospital, Niyayesh St, Sattarkhan St

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6653 9260

Fax

+98 21 6653 9260

Email

moradimoghadam.o@iums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Abbas Motavalian

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

research@iums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Maziar Emamikhah

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Rasoul Akram hospital, Niyayesh St, Sattarkhan St

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6653 9260

Email

maziar.emamikhah@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maziar Emamikhah

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Rasoul Akram hospital, Niyayesh St, Sattarkhan St

City

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Province

Tehran

Postal code

1445613131

Phone

+98 21 6653 9260

Email

maziar.emamikhah@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maziar Emamikhah

Position

Associate professor

Latest degree

Specialist

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Phone

+98 21 6653 9260

Email

maziar.emamikhah@yahoo.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

No - There is not 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

No - There is not 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