Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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. Medafinil 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 conscioousness. 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

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Omid Moradi Moghadam

Name of organization / entity
Iran University of Medical Sciences

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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 consiousness, drowsiness to deep coma
Exclusion criteria:
History of seizure Clinical feature accompanied after drug cosumption 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 consiousnesa
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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

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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
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