Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Investigation of the effect of modafinil on respiratory and cerebral consequences after coronary artery bypass graft surgery

Protocol summary

Study aim

Investigation of the effect of modafinil on respiratory and cerebral consequences after coronary artery bypass graft surgery

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 74 patients. The rand function of the Excel software was used for randomization.

Settings and conduct

The study is being performed at the Shahid Chamran Heart Medical Center in Isfahan on patients who are candidates for coronary artery bypass graft surgery, during which surgery is started after induction of anesthesia. Arterial blood samples are taken from all patients, and this is done every hour until the end of the operation. After the patient is wening from the cardiopulmonary bypass pump, a simple, individual randomized delivery of modafinil at a dose of 200 mg is given to the patient by the intervention group and the placebo is given to the patient by the control group orally with a nasogastric tube. After the surgery, the patients are transferred to the intensive care unit and arterial blood samples are taken from the patients, and this is done every three hours until the end of the hospitalization period. Once patients are awake and the level of consciousness is checked by the Richmond-Agitation Scale, it is done every hour until they reach full consciousness.

Participants/Inclusion and exclusion criteria

Patients with coronary artery bypass graft surgery with a cardiac ejection fraction of more than 40% and without liver and kidney dysfunction and without irregular primary rhythm and cardiomegaly.

Intervention groups

After weaning of the patient from the cardiopulmonary bypass pump, the modafinil is given at a dose of 200 mg to the patient of the intervention group and the placebo is given to the control group orally with a nasogastric tube.

Main outcome variables

Check the duration of hospital stay, Results and quality of life And check readmission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200611047728N1**
Registration date: **2020-08-06, 1399/05/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-06, 1399/05/16**
Update count: **0**

Registration date

2020-08-06, 1399/05/16

Registrant information

Name

Mohammad Kazem Rezaei Hosein Abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3261 1400

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drmkrezaei_62@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-30, 1399/04/10

Expected recruitment end date

2020-08-31, 1399/06/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the effect of modafinil on respiratory and cerebral consequences after coronary artery bypass graft surgery

Public title
Investigation of the effect of modafinil in coronary artery bypass graft surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
patients with coronary artery bypass graft surgery patients with a cardiac ejection fraction of more than 40%
Exclusion criteria:
Patients with hepatic function failure Patients with renal function failure Patients with irregular cardiac primary rhythms Patients with cardiomegaly patients who have drug addiction patients who have alcoholism patients who are using psychiatric drugs
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization: Simple randomization, randomization unit: individual, randomization tool: randomized number table. The couple numbers will be in the intervention group and the odd numbers will be in the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The control drug is similar in appearance to the modafinil drug and is given to the patient by a person who has no role in the test, and then the information is collected by the same person
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hezarjerib St. Isfahan University of Medical Sciences, School of Medicine
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2020-06-29, 1399/04/09
Ethics committee reference number
IR.MUI.MED.REC.1399.265

Health conditions studied

1

Description of health condition studied
respiratory and cerebral outcomes
ICD-10 code
J96.92, F1
ICD-10 code description
Respiratory failure, unspecified with hypercapnia, Sedative, hypnotic or anxiolytic use, unspecified with sedative, hypnotic or anxiolytic-induced sleep disorder

Primary outcomes

1

Description
The time to reach full consciousness
Timepoint
Every hour until you reach full consciousness
Method of measurement
Richmond-Agitation Scale

2

Description
Duration of mechanical ventilation in the intensive care unit
Timepoint
Every hour until you reach full consciousness
Method of measurement
In minutes using time meter

3

Description
Length of stay in Intensive Care Unit
Timepoint
Every day until discharge from Intensive Care Unit
Method of measurement
By day using Count days

4

Description
Carbon dioxide arterial pressure
Timepoint
Every one hour
Method of measurement
Arterial blood samples based on mercury mm

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: After induction of anesthesia and endotracheal intubation, surgery will begin and after isolation of the patient from cardiopulmonary pump, modafinil (the drug is produced by Sobhan Daru Company) will be given to the patient orally with nasogastric tube by a person who has no role in the test. On the second morning of hospitalization, 200 mg modafinil will be given to patients in the intervention group orally by a person who has no role in the test.
Category
Treatment - Drugs

2

Description
Control group: After induction of anesthesia and endotracheal intubation, surgery will begin and after isolation from cardiopulmonary pump, the patient will be given placebo randomly and individually to the control group orally with nasogastric tube by a person who has no role in the test. On the second morning of hospitalization, the second dose of placebo will be given to the patient in the control group orally by a person who has no role in the test.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran University, Health and Research Center
Full name of responsible person
Dr. Mojtaba Mansouri
Street address
Shahid Chamran Hospital, Bozorgmehr Bridge, 3rd moshtagh Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Shaghayegh Haghjooy Javanmard
Street address
Isfahan University of Medical Sciences and health services, Hezar jerib St.
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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
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Mojtaba Mansouri

Position
Associate Professor, Department of Anesthesiology, Isfahan University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Shahid Chamran Hospital, Bozorgmehr Bridge, third moshtagh Street

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Associate Professor, Department of Anesthesiology, Isfahan University of Medical Sciences

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Latest degree
Specialist

Other areas of specialty/work
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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