

# 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)

##### Phone

+98 31 3261 1400

##### Email address

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**

Isfahan

**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

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8166173414

#### **Phone**

+98 31 3261 1400

#### **Fax**

+98 31 3261 1405

#### **Email**

Drmkrezaei\_62@yahoo.com

## **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.

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

81746-73461

##### **Phone**

+98 31 3668 8138

##### **Fax**

+98 31 3668 7898

##### **Email**

Drmkrezaei\_62@yahoo.com

#### **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

**Street address**

Shahid Chamran Hospital, Bozorgmehr Bridge, third  
moshtagh Street

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Mojtaba Mansouri

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**

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**Email**

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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