

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### Effect of modafinil for prevention of cognitive and sociological dysfunction after sleeve gastrectomy

#### Protocol summary

##### Study aim

To investigate the effect of modafinil for prevention of cognitive and sociological dysfunction after sleeve gastrectomy

##### Design

Double Blinded Randomized Clinical Trial

##### Settings and conduct

80 patients undergoing sleeve gastrectomy are divided into two groups of 40. Patients in the first group received 2 tablets of modafinil 100 mg two hours before the operation and patients in the second group received 2 tablets of placebo two hours before the operation. The investigator determines the type of drug or placebo and provides them to the nurse for prescribing to the patient. The patient and the person evaluating the patient after the surgery are unaware of the type of intervention. The patients will be evaluated the day before the surgery and after leaving the recovery room by two tests of Addenbrooke's Cognitive Examination (ACE) for Cognitive problems and also Depression and Anxiety Scale, DASS-21 for Depression and Anxiety.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidate for elective sleeve gastrectomy ASA I-II age between 18-45 years' old. Exclusion criteria: Active and uncontrolled diseases of the cardiovascular system; Gastrointestinal diseases; Liver and kidney Diseases; Psychological and mental illness; Neurological diseases; Taking psychiatric medications; opium addiction.

##### Intervention groups

patients in the first group received 2 tablets of modafinil 100 mg two hours before the operation and patients in the second group received 2 tablets of placebo two hours before the operation.

##### Main outcome variables

Depression and Anxiety and Cognitive problems

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141009019470N76**

Registration date: **2018-09-06, 1397/06/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-06, 1397/06/15**

Update count: **0**

##### Registration date

2018-09-06, 1397/06/15

##### Registrant information

##### Name

Farzaneh Masihi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4270

##### Email address

masihif@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-01, 1397/06/10

##### Expected recruitment end date

2019-02-25, 1397/12/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of modafinil for prevention of cognitive and sociological dysfunction after sleeve gastrectomy

#### Public title

Effect of modafinil for prevention of cognitive and sociological dysfunction after sleeve gastrectomy

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients who are candidate for elective sleeve gastrectomy ASA I-II age between 18-45 years old

##### Exclusion criteria:

Active and uncontrolled diseases of the cardiovascular system. Gastrointestinal diseases. Liver disease. kidney Diseases. Psychological and mental illness. Neurological diseases. Taking psychiatric medications. opium addiction

#### Age

From **18 years** old to **45 years** old

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

- Participant
- Care provider
- Outcome assessor

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients were randomized according to the charts which was derived from www.randomization.com site.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The investigator determines the type of drug or placebo based on the randomized list and provides drug or placebo to the nurse in the ward for prescribing to the patient. The patient and the person evaluating the patient after the surgery are unaware of the type of intervention.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics Committee of Shiraz University of Medical

Sciences

#### Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

#### City

Shiraz

#### Province

Fars

#### Postal code

7134844119

#### Approval date

2017-08-23, 1396/06/01

#### Ethics committee reference number

IR.SUMS.MED.REC.1396.63

### Health conditions studied

#### 1

##### Description of health condition studied

sleeve gastrectomy

##### ICD-10 code

K95.89

##### ICD-10 code description

Other complications of other bariatric procedure

### Primary outcomes

#### 1

##### Description

Depression and Anxiety

##### Timepoint

The day before the surgery and after leaving the recovery room.

##### Method of measurement

Depression and Anxiety Scale, DASS-21

#### 2

##### Description

Cognitive problems

##### Timepoint

The day before the surgery and after leaving the recovery room.

##### Method of measurement

The Addenbrooke's Cognitive Examination (ACE)

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group:patients received 2 tablets of modafinil 100 mg two hours before the operation.

##### Category

Prevention

**2**

**Description**

Control group: patients received 2 tablets of placebo two hours before the operation.

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mother and Child Hospital

**Full name of responsible person**

Kambiz Golestani

**Street address**

Mother and Child Hospital, Quran square, Emam Reza boulevard,

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**Email**

masihifarzaneh@yahoo.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Seed Basir Hashemi

**Street address**

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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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**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Kambiz Golestani

**Position**

Anesthesiology resident/physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand Street

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mehrdad Salari

**Position**

Anesthesiologist

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh Masihi

**Position**

MS in English Teaching, BS in anesthesia/English  
Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Others

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5th floor, Mohammad Rasoul Allah Research Tower,  
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**Postal code**

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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