

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Sep 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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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

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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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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