

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of nutritional status and mental health of patients before and after the bariatric surgery with three operational methods.

Protocol summary

Study aim

The aim of this study is to determine the nutritional status and mental health of individuals before and after the bariatric surgery with three operational methods; bypass classic, mini bypass and sleeve

Design

This study is carried out on 120 men and women. Before the operation, the nutritional status and mental health of patients are determined using a questionnaire and an interview and Patients undergo bariatric surgery. In the following year after operation, patients are assessed to re-evaluate their nutritional status and mental health.

Settings and conduct

This study will be conducted on patients undergoing obstructive surgery referred to obesity clinic of Firoozgar Hospital.

Participants/Inclusion and exclusion criteria

The inclusion criteria are obese patients in the age range of 18-65 years. Exclusion criteria are those patients who consume any psychoactive drugs and antidepressants.

Intervention groups

The intervention group are candidates for bariatric surgery that they are self-proclaimed for this practice. This study does not have a control group.

Main outcome variables

Axis I disorders: Contains clinical disturbances and other disorders that may be of clinical interest. eating disorders: any of a range of psychological disorders characterized by abnormal or disturbed eating habits (such as anorexia nervosa).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130508013273N3**

Registration date: **2018-06-05, 1397/03/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-05, 1397/03/15**

Update count: **0**

Registration date

2018-06-05, 1397/03/15

Registrant information

Name

Behrooz Ghanbari

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4472 9733

Email address

b.ghanbari@hotmail.com

Recruitment status

Recruitment complete

Funding source

Government funds will be used.

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of nutritional status and mental health of patients before and after the bariatric surgery with three operational methods.

Public title

The effect of bariatric surgery with three operational methods (bypass classic, mini bypass and sleeve) on patients' nutritional status and mental health.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The inclusion criteria are obese patients in the age range of 18-65 years.

Exclusion criteria:

Exclusion criteria are those patients who consume any psychoactive drugs and antidepressants

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Firoozgar hospital., Valadi Ave., Valiasr sq

City

Tehran

Province

Tehran

Postal code

1593747811

Approval date

2017-12-12, 1396/09/21

Ethics committee reference number

IR.IUMS.REC 1395.95-03-143-29655

Health conditions studied

1

Description of health condition studied

obesity

ICD-10 code

E66.01

ICD-10 code description

Morbid (severe) obesity due to excess calories

Primary outcomes

1

Description

eating disorder

Timepoint

Before intervention, 1 year after intervention

Method of measurement

Eating Disorders Questionnaire (EDE_Q 6.0)

2

Description

psychological disorder

Timepoint

Before intervention, 1 year after intervention

Method of measurement

The DSM-IV semi-structured questionnaire

Secondary outcomes

1

Description

body composition

Timepoint

Before intervention, 1 year after intervention

Method of measurement

In Body 720(body composition analysers)

2

Description

physical activity

Timepoint

Before intervention, 1 year after intervention

Method of measurement

IPAQ (International Physical Activity Questionnaire)

Intervention groups

1

Description

Before the operation, the nutritional status and mental health of patients are determined using a questionnaire and an interview and Patients undergo bariatric surgery. In the following year after operation, patients are assessed to re-evaluate their nutritional status and mental health.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Firozgar Hospital

Full name of responsible person

Behrooz Ghanbari, Ph.D by research

Street address

Valadi St, Valiasr Sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Behrooz Ghanbari

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Shahid Hemmat Highway

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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

Firozgar hospital

Full name of responsible person

Behrooz Ghanbari

Position

Hospital Manager

Latest degree

Ph.D.

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Behrooz Ghanbari

Position

Ph.D by research

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

Contact

Name of organization / entity

Firozgar Hospital

Full name of responsible person

Behrooz Ghanbari

Position

Hospital Manager

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Fax**Email**

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Web page address**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