Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

City
Tehran

Province
Tehran

Postal code
1593747811

Phone
+98 21 8214 1303

Email
b.ghanbari@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran Univercity of Medical Sciences

Full name of responsible person
Behrooz Ghanbari

Street address
Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1593747811

Phone
+98 21 8214 1303

Email
b.ghanbari@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran Univercity 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
Firoozgar hospital

Full name of responsible person
Behrooz Ghanbari

Position
Hospital Manager

Latest degree
Ph.D.

Other areas of specialty/work
Psychiatrics

Street address
Valadi st, Valiasr sq.

City
Tehran

Province
Tehran

Postal code
1593747811

Phone
+98 21 8214 1303

Fax

Email
g.behrooz@gmail.com

Web page address

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

Street address
Valadi st, Valiasr sq.

City
Tehran

Province
Tehran

Postal code
1593747811

Phone
+98 21 8214 1303

Fax

Email
g.behrooz@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Firoozgar Hospital

Full name of responsible person
Behrooz Ghanbari
Position
Hospital Manager
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Valadi Ave, Valiasr sq.
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1303
Fax
Email
g.behrooz@gmail.com
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