Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Bariatric Surgery on alterations of refractive errors in patients with morbid obesity

Protocol summary

Summary

Eye refractive disorders are among the most common human problems basically depend on genetic disturbances and may alter with systemic diseases. The aim of this study is the evaluation of the changes of refractive disorders in morbid obese patients whom undergo bariatric surgery and loose weight. Inclusion criteria are morbid obesity candidate for bariatric surgery, (BMI > 40, or BMI > 35 + at least one underlying disorder). Exclusion criteria are ophthalmic underlying diseases or blindness binocularly. 60 patients with the above conditions will undergo ophthalmic exams, by an optometrist, before and again after the bariatric surgery in minimally invasive research center of Tehran University of Medical Sciences.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202168588N2**
Registration date: **2012-04-22, 1391/02/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-04-22, 1391/02/03

Registrant information

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Mohadeseh Pishgahroudsari
Name of organization / entity
Mnimally Invasive Surgery Research Center
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Bariatric Surgery on alterations of refractive errors in patients with morbid obesity

Public title

Evaluation of Bariatric Surgery on alterations of refractive errors in patients with morbid obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : patients should not be blind they have to be a candidate for Bariatric Surgery؛ BMI should be 40 and over and if it is between 35 and 40؛ then patient should have an underlying risk factor. Exclusion criteria: patients should not have any previous underlying eye diseases؛Patients who are blind.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Tehran University of Medical science
Street address
Tehran University of Medical Sciences-Corner of Ghods-Keshavarz Blvd-Tehran-Iran
City
Tehran
Postal code
Approval date
2012-01-31, 1390/11/11
Ethics committee reference number
45001

Health conditions studied

1

Description of health condition studied
Myopia
ICD-10 code
H52.5
ICD-10 code description
Disorders of accommodation

2

Description of health condition studied
Hyperopia
ICD-10 code
H52.0
ICD-10 code description
Disorders of accommodation

Primary outcomes

1

Description
Visual acuity
Timepoint
Before intervention and 6 months after intervention
Method of measurement
Log Minimum Angle of Resolution-snellen chart

2

Description
Cover test
Timepoint
Before Surgery and 6 month afterward
Method of measurement
Prism

3

Description
Keratometry
Timepoint
Before Surgery and 6 month afterward
Method of measurement
Millimeter

4

Description
Lensometry
Timepoint
Before Surgery and 6 month afterward
Method of measurement
Diopter

5

Description
Retinoscopy
Timepoint
Before Surgery and 6 month afterward
Method of measurement
Diopter

6

Description
Ophthalmoscopy
Timepoint
Before Surgery and 6 month afterward
Method of measurement
Ophthalmoscope

Secondary outcomes

1

Description
Sex
Timepoint
Before surgery
Method of measurement

Male and Female

2

Description
BMI
Timepoint
Before surgery and 6 month afterward
Method of measurement
Weight in Kg/Squared Height in Meter

3

Description
Age
Timepoint
before surgery and 6 month afterward
Method of measurement
Year

Intervention groups

1

Description
Laparoscopic Bariatric Surgery
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Minimally Invasive Surgery Research Center, Tehran University of Medical Sciences.
Full name of responsible person
Mrs.Mohadeseh Pishgah
Street address
Niyayesh Ave, Sattarkhan St., Minimally Invasive Surgery Research Center, Rasool-e-Akram Hospital, Tehran, Iran.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Terarn university of Medical science.
Full name of responsible person
Dr. Fotouhi
Street address
Corner of Ghods, Keshavarz Blvd., Tehran University of Medical Sciences, Tehran, Iran.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Terarn university of Medical science.
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Minimally Invasive Surgery Research Center, Tehran University of Medical Sciences.
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty