

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Mohadeseh Pishgahroudsari

Name of organization / entity

Mnimally Invasive Surgery Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 5447

Email address

research@lapsurg.ir

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.

Full name of responsible person

Khashayar Mehizadehkashi

Position

Last Course Student of BS in Optometry

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Minimally Invasive Surgery Research Center, Tehran
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Full name of responsible person

Dr.Abdolreza Pazouki

Position

Laparoscopy Fellowship

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Minimally Invasive Surgery Research Center
Full name of responsible person
Mohadeseh pishgah-Roudsari
Position
Research and Statistic Expert
Other areas of specialty/work
Street address
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Phone

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