

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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.

##### 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

#### 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

##### 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 Mehidzadehkashi

#### Position

Last Course Student of BS in Optometry

#### Other areas of specialty/work

#### Street address

App. 3 west, No. 11, Saeedi Ave. Fereshteh St.  
Valieasr St.

#### City

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#### Postal code

#### Phone

+98 21 2264 8334

#### Fax

#### Email

amoo\_khashi@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Minimally Invasive Surgery Research Center, Tehran  
University of Medical Sciences.

#### Full name of responsible person

Dr.Abdolreza Pazouki

#### Position

Laparoscopy Fellowship

#### Other areas of specialty/work

#### Street address

Niyayesh Ave, Sattarkhan St., Minimally Invasive  
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**Email** mo.pishgah@gmail.com,research@lapsurg.ir  
**Web page address**

## 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**  
Niyayesh Ave, Sattarkhan St., Minimally Invasive  
Surgery Research Center, Rasool-e-Akram Hospital,  
Tehran, Iran.  
**City**  
Tehran  
**Postal code**  
**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*