

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Effect of reduction in fat mass measured by body composition after laparoscopic Bariatric surgery on the return of ovarian function in women with morbid obesity and anovulation

#### Protocol summary

##### Summary

The purpose of this study is the assessment of Bariatric surgery effect on the treatment of anovulation in morbid obese women who have anovulation problem. In this study patients with morbid obesity( BMI >35 with a comorbidity or BMI>40 ) : at Age of 15-45 years with anovulation problem who are candidate for Bariatric Laparoscopic surgery because of morbid obesity are selected and patients with Thyroid disease and Pregnancy are excluded. Morbid obese women who come to obesity clinic of Rasool-e-Akram Hospital are studied; sample size of this study is estimated 60 patients. In this study the effect of bariatric surgical intervention in the treatment of anovulation in morbid obese women in the years 1391-1392 are evaluated. We can assess ovulation or anovulation after surgery by measuring Luteinizing hormone level on third day of menstrual cycle.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201203078588N4**

Registration date: **2012-06-02, 1391/03/13**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-06-02, 1391/03/13

##### Registrant information

###### Name

Mohadeseh Pishgahroudsari

###### Name of organization / entity

Minimally 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

2012-04-20, 1391/02/01

###### Expected recruitment end date

2015-04-21, 1394/02/01

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Effect of reduction in fat mass measured by body composition after laparoscopic Bariatric surgery on the return of ovarian function in women with morbid obesity and anovulation

###### Public title

Effect of reduction in fat mass after laparoscopic obesity on women with ovulation

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: BMI>40 or >35 with a comorbidity:

Anovulation proved by lab data: Age of 15-45 years.

Exclusion criteria: Pregnancy: Thyroid problems.

###### Age

From **15 years** old to **45 years** old

###### Gender

Female

## Phase

N/A

## 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

Ethics Committee of Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., Tehran, Iran.

##### City

Tehran

##### Postal code

#### Approval date

2012-01-31, 1390/11/11

#### Ethics committee reference number

45018

## Health conditions studied

### 1

#### Description of health condition studied

Anovulation in women

#### ICD-10 code

N97.0

#### ICD-10 code description

N97.8

## Primary outcomes

### 1

#### Description

BMI

#### Timepoint

Three months after intervention

## Method of measurement

Weight divided by the square of height in centimeters

### 2

#### Description

LH

#### Timepoint

Three months after intervention

#### Method of measurement

Using laboratory kits

## Secondary outcomes

### 1

#### Description

FSH

#### Timepoint

Three months after Intervention

#### Method of measurement

Using laboratory kits

### 2

#### Description

Fat Mass

#### Timepoint

Three months after Intervention

#### Method of measurement

Bio-impedance device

### 3

#### Description

Prolactin

#### Timepoint

Three months after Intervention

#### Method of measurement

Using laboratory kits

## Intervention groups

### 1

#### Description

Laparoscopic bariatric surgery

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasool-e-Akram Hospital

##### Full name of responsible person

Zeinab Tamannaie

##### Street address

Minimally Invasive Surgery Research Center, Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St.,

Tehran, Iran.

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences.

**Full name of responsible person**

Dr.Akbar Fotouhi

**Street address**

Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., 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**

Tehran University of Medical Sciences.

**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**

Dr.Zeinab Tamanaie

**Position**

GP

**Other areas of specialty/work**

**Street address**

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zeinab\_tamannaie@yahoo.com

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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

**Full name of responsible person**

Dr.Shahla Chaichian

**Position**

Laparoscopic Fellowship Women's Cancer

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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

**Full name of responsible person**

Mohadeseh pishgah Roudsari

**Position**

Expert Stats

**Other areas of specialty/work**

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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*