

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 Rasoole-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

Mnially 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

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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

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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