

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of effect of urinary catheterization in morbid obese patients are undergone bariatric laparoscopic surgery versus patient without catheterization on urinary complication of surgery

#### Protocol summary

2012-08-07, 1391/05/17

#### Summary

This is an interventional study to compare urinary catheterization in patients undergone bariatric laparoscopic surgery versus patient without catheterization and assess the urinary complications after surgery in this 2 groups of morbid obese patients . The study includes morbid obese patients undergone bariatric laparoscopic surgery and the patients with urinary disorder and who needs to ICU care before or after surgery are excluded . also the study doesn't include patients if the surgery convert to open or takes more than 4 hours. the population of study are patients with morbid obesity who randomly are divided in two groups of 40 patients. For case group, urinary catheterization during surgery isn't done and if the surgery of these patients take more than two hours, after surgery, urinary bladder will be empty by temporary catheter. in the control group, preoperative urinary catheterization is done and 24 hours after surgery it will be removed. in both groups after surgery, on day of surgery , first and second day after surgery ,the urine volume, urinary infection , retention , urinary incontinence the level of Satisfaction of catheterization and the probably problems with urinary tract are valued by asking , patient examination and lab test if needed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201206108588N7**  
Registration date: **2012-08-07, 1391/05/17**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

#### 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

2012-06-01, 1391/03/12

#### Expected recruitment end date

2013-11-30, 1392/09/09

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of effect of urinary catheterization in morbid obese patients are undergone bariatric laparoscopic surgery versus patient without catheterization on urinary complication of surgery

#### Public title

Comparison of complications in Morbid obese patients undergone bariatric laparoscopic surgery with and without urinary catheterization

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: the patients with BMI >35 with comorbidities or BMI>40 who candidate for bariatric laparoscopic surgery. Exclusion criteria: the patients with urinary disorder; the patients who needs to ICU care before or after surgery; patients who their surgery is converted to open; the patients who are undergone surgery more than 4 hours.

## Age

From **16 years** old to **64 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

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

2012-06-24, 1391/04/04

#### Ethics committee reference number

17551

## Health conditions studied

### 1

#### Description of health condition studied

urinary Catheterization

#### ICD-10 code

Y84.6

#### ICD-10 code description

Urinary catheterization

### 2

#### Description of health condition studied

urinary tract infection

#### ICD-10 code

N39.0

#### ICD-10 code description

Urinary tract infection, site not specified

### 3

#### Description of health condition studied

urinary retention

#### ICD-10 code

R33

#### ICD-10 code description

Retention of urine

## Primary outcomes

### 1

#### Description

Urinary Tract Infection

#### Timepoint

after Intervention,one day after intervention, Two days after intervention

#### Method of measurement

Urine culture

### 2

#### Description

urinary Incontinency

#### Timepoint

after Intervention,one day after intervention, two days after intervention

#### Method of measurement

The patient complained

## Secondary outcomes

### 1

#### Description

Foreign body sensation

#### Timepoint

after intervention,one day after intervention,two day after intervention

#### Method of measurement

Question

## Intervention groups

### 1

#### Description

For intervention group, urinary catheterization during

surgery isn't done and if the surgery of these patients take more than two hours, after surgery, urinary bladder will be empty by temporary catheter.

**Category**

Other

**2**

**Description**

in the control group, preoperative urinary catheterization is done and 24 hours after surgery it will be removed.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Rasool-e-Akram Hospital

**Full name of responsible person**

**Street address**

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

**Full name of responsible person**

Dr.Mohsen Kalhor

**Position**

Laparoscopic Fellowship

**Other areas of specialty/work**

**Street address**

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

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

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**Other areas of specialty/work**

**Street address**

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**Full name of responsible person**

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**Position**

Expert Stats

**Other areas of specialty/work**

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**Email**

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**Web page address**

**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*