Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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

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

2012-08-07, 1391/05/17

Registrant information

Name
Mohadeseh Pishgahroudsari
Name of organization / entity
Mnimally Invasive Surgery Research Center
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Iran (Islamic Republic of)
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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 surgrey 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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mohadeseh Pishgah

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