Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Overactive bladder symptoms in women with pelvic organ prolapse before and after surgery

Protocol summary

Summary

Objectives: Main goal of this study is evaluation of overactive bladder symptoms in women with pelvic organ prolapse before and after surgery in comparison with antimuscarinic drugs. Setting and conduct: To evaluate the effect of obliterative or reconstructive surgery on recovery of overactive bladder. Before surgery, patients will be thorough history taking and pelvic examination will be complete. Before surgery, pelvic organ prolapse grade will be determined according to pelvic organ prolapse grading system. After collecting data, they will be entered in SPSS and will be analyzed. Inclusion criteria: All women with all grades of genital prolapse who can also respond to the questionnaire; Women who will be undergoing obliterative or reconstructive surgery early; Women who enrolled in the study from January 2013 to January 2014 and will be follow up for one year. It will be available or convenient sampling method. Exclusion criteria: No satisfaction to enter the study will be the exclusion criteria. Main outcome measures: Frequent urination, Urinary urgency and Urge incontinence will be evaluated before the intervention and six months after the intervention. These symptoms will be assessed using selected questions from Pelvic Floor Distress Inventor (PFDI) valid questionnaire that is related to urinary distress.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020626387N1**
Registration date: **2016-02-24, 1394/12/05**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-24, 1394/12/05

Registrant information

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Kima Rahmati
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Overactive bladder symptoms in women with pelvic organ prolapse before and after surgery

Public title

Overactive bladder symptoms in women with pelvic organ prolapse before and after surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All women with all grades of genital prolapse who can also respond to the questionnaire; Women who will be undergoing obliterative or reconstructive surgery early; Women who enrolled in the study from January 2013 to January 2014 and will be follow up for one year. Exclusion criteria: All patients who had incomplete information in their files; No satisfaction to enter the study.

Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **159**
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
Ethics committee of Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Qods St., Keshavarz Blvd., Tehran, Iran * آدرس Tehran
City
Tehran
Postal code
Approval date
2016-01-25, 1394/11/05
Ethics committee reference number
IR.TUMS.REC.139401744

Health conditions studied

1

Description of health condition studied
Overactive bladder
ICD-10 code
N32.8
ICD-10 code description
Other specified disorders of bladder

2

Description of health condition studied
Pelvic organ prolapse
ICD-10 code
N81.8
ICD-10 code description
Other female genital prolapse

Primary outcomes

1

Description
Frequent urination
Timepoint
At the beginning of the intervention, six months after the intervention, twelve months after the intervention
Method of measurement
Pelvic floor distress inventor questionnaire (PFDI)

2

Description
Urinary urgency
Timepoint
At the beginning of the intervention, six months after the intervention, twelve months after the intervention
Method of measurement
Pelvic floor distress inventor questionnaire (PFDI)

3

Description
Urge incontinence
Timepoint
At the beginning of the intervention, six months after the intervention, twelve months after the intervention.
Method of measurement
Pelvic floor distress inventor questionnaire (PFDI)

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Intervention group: surgery
Category

Treatment - Surgery

2

Description
Control group: antimuscarinic drugs for 6 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Urology Research Center of Sina hospital
Full name of responsible person
Ozra Azmoodeh
Street address
Urology Research Center of Sina hospital, Sina Hospital, Imam Khomeini St.
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Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Tehran University of Medical Sciences
Full name of responsible person
Masud Yunesian
Street address
Vice Chancellor for research of Tehran University of Medical Sciences, 6 floor, TUMS building, at the corner of Qods St., Keshavarz Blvd.
City
Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of 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
Moheb Yas women general hospital
Full name of responsible person
Dr. Kima Ghaed Rahmati
Position
Senior resident in obstetrics and gynecology
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Person responsible for updating data

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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