Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Exploring the effect of performing pelvic floor muscles strengthening exercises on post-prostatectomy patients' urinary incontinence and quality of life

Protocol summary

Summary

The aim of this study is to determine the effect of training pelvic-floor muscles on post-prostatectomy patients' urinary incontinence and quality of life. This study will be a randomized clinical trial. Sixty patients who are suffering from benign prostate hypertrophy (BPH) will participate in the study after meeting the study inclusion criteria and signing written informed consent. Accordingly, they will be allocated to control and experiment groups through blocked randomized method. The inclusion criteria for the participants includes: seeking candidacy to undergo suprapubic prostate surgery, being literate enough to read and write, and aging between 50 and 75 years old. Meanwhile, the patients who are unwilling to participate in the study or to change the dosage of the medication prescribed for their urinary incontinence will be excluded from the study. The research will be carried out as follows: initially, both groups will fill in the demographic, urinary incontinence and quality of life questionnaires prior to intervention. Then, the experiment group will be trained by the researcher for pelvic-floor muscles exercises (PFMEs) while the control group uses only the routine trainings in ward. The PFMEs will be performed 3 times a day within 12 weeks nonstop. Patients will primarily do the contractions for 3 seconds and relax for 5 seconds afterward. Then, the number of contractions will be gradually increased to 90-100 per day. Self-report checklists and educational pamphlets about prostate surgery urinary incontinence and pelvic-floor muscles exercising will be given to the experiment group. Patients will fill in the urinary incontinence and quality of life questionnaires at the end of the third month. Finally, the data from the control and the experiment groups will be compared with each other. The researcher will attend urology clinic once a week while contacting the patients on phone every week in the first month, and at the end of the second and third months throughout the research.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2014090519049N1**
Registration date: **2014-11-14, 1393/08/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-14, 1393/08/23

Registrant information

Name
Majid Rai
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-07-15, 1393/04/24

Expected recruitment end date

2014-10-16, 1393/07/24

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Exploring the effect of performing pelvic floor muscles strengthening exercises on post-prostatectomy patients' urinary incontinence and quality of life

Public title
The effect of pelvic-floor muscles exercises and in-ward routine trainings on urinary incontinence and quality of life among post-prostatectomy patients
Purpose
Health service research
Inclusion/Exclusion criteria
The inclusion criteria included of: seeking candidacy to undergo suprapubic prostate surgery, being literate enough to read and write, and aging between 50 and 75 years old. Exclusion criteria : Patients who were unwilling to participate in the study or to change the dosage of the medication prescribed for their urinary incontinence were excluded from the study
Age
From **50 years** old to **75 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size:
Randomization (investigator's opinion)
Randomized
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 Science
Street address
Sixth Floor, Central Organization of University, Qods St, Keshavarz Blvd
City
Tehran
Postal code
-
Approval date
2014-07-15, 1393/04/24
Ethics committee reference number
130/914/93/د

Health conditions studied

1

Description of health condition studied
Urinary incontinence
ICD-10 code
N39.4
ICD-10 code description
Other specified urinary incontinence

Primary outcomes

1

Description
Urinary incontinence
Timepoint
Before training and after three months of training
Method of measurement
Questionnaire ICIQ-UI SF

Secondary outcomes

1

Description
Quality of Life
Timepoint
Before training and after three months of training
Method of measurement
Questionnaire I QOL

Intervention groups

1

Description
The PFMEs will be performed 3 times a day for 12 weeks nonstop in the experiment group through which the patients will initially do the contractions for 3 seconds and relax for 5 seconds afterward. Then, the number of contractions will be gradually increased to 90-100 times per day.
Category
Rehabilitation

2

Description
In the meantime, the control group will not receive any PFMEs and it uses only the routine trainings in the ward.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Urology clinic of Vali Asr Naja Hospital in Tehran
Full name of responsible person
Majid Rai
Street address
Vali Asr St, Vanak Sq , Rashid Yasami St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Doctor Masood Younesian-Vice President of Research and Technology
Street address
Keshavarz St, Qods St., Central Building, Sixth Floor, Tehran University of Medical Sciences, Tehran
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, 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
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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