

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

Country

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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

130/914/93/3

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

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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

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Keshavarz St, Qods St., Central Building, Sixth Floor, Tehran University of Medical Sciences, Tehran

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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**

Tehran University of Medical Sciences

Full name of responsible person

Majid Rai

Position

Nursing Graduate Student

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Doctor Shokouh Varaei

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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