Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of pelvic floor muscle exercises (Kegel training) on improving patient’s quality of life and urinary incontinence after radical prostatectomy

Protocol summary

Study aim

The primary purpose of this project is to determine the effect of pelvic floor muscle training on improving the quality of life and urinary incontinence of the patients after radical prostatectomy.

Design

This clinical trial has a sample size of 80 individuals, randomized using random allocation software, is without a control group, community-based, and pragmatic, with parallel groups and double-blind.

Settings and conduct

Participants are selected after evaluating inclusion and exclusion criteria and assigned randomly to the control group or the Kegel training recipient group. After obtaining the demographic information of the patients, a physiotherapist will provide the necessary lessons to the intervention group during a one-hour session.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 50 and 75 years old; being a candidate for prostatectomy surgery; informed consent for participation in the study. Exclusion criteria: presence of Diabetes mellitus; neurological deficits; psychological deficits; having severe urinary incontinence prior to the surgical intervention.

Intervention groups

The intervention group is provided with training lessons for strengthening pelvic floor muscles using a biofeedback technique and are given a home exercise program. For one month each day, they will do the exercises at home. The control group does not receive pelvic floor muscle training lessons. Then, both groups of patients undergo radical prostatectomy and the intervention group continues the training for 6 months.

Main outcome variables

Quality of life and postoperative urinary incontinence status based on the questionnaire score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170716035104N3**
Registration date: **2019-04-22, 1398/02/02**
Registration timing: **retrospective**

Last update: **2019-04-22, 1398/02/02**
Update count: **0**

Registration date

2019-04-22, 1398/02/02

Registrant information

Name

Roham Nik Khah

Name of organization / entity

Medical University of Isfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

2016-06-30, 1395/04/10

Actual recruitment end date

2017-07-23, 1396/05/01

Trial completion date

2018-03-11, 1396/12/20

Scientific title
The effect of pelvic floor muscle exercises (Kegel training) on improving patient’s quality of life and urinary incontinence after radical prostatectomy

Public title
The effect of Kegel training on quality of life and urinary incontinence after radical prostatectomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 50 and 75 years old Being a candidate for prostatectomy surgery Informed consent for participation in the study

Exclusion criteria:
Presence of Diabetes mellitus Neurological deficits Psychological deficits Having severe urinary incontinence prior to the surgical intervention Age over 75 years due to the high prevalence of geriatric incontinence and severe pelvic floor muscle breakdown Unavailability of the patient or the inability to follow the patient Patient's death after surgery Admission to ICU due to grade 3 and 4 post-operative complications

Age
From **50 years** old to **75 years** old

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done using "Simple Random Sampling" method and random value creation between zero and one in SPSS software. To allocate random values to the intervention group or control group a value less than or equal to 0.5 is assigned to the control group and values greater than 0.5 are assigned to the intervention group by sortition.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants will not be informed about the group they are dedicated to (intervention or control). Moreover, clinical caregivers will not be informed about the patient's group (intervention or control). Researcher and the outcome evaluators will not be blinde due to the necessity for patient follow-up.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan, Iran.

City
Isfahan

Province
Isfehan

Postal code
7346181746

Approval date
2017-06-03, 1396/03/13

Ethics committee reference number
IR.MUI.REC.396.926

Health conditions studied

1

Description of health condition studied
Prostate cancer

ICD-10 code
C79.1

ICD-10 code description
Secondary malignant neoplasm of bladder and other and unspecified urinary organs

Primary outcomes

1

Description
International Consultation on Incontinence Questionnaire. Male Lower Urinary Tract Symptoms long form questionnaire scores

Timepoint
One day, one week, one month, three months and six months after the surgery

Method of measurement
Evaluating the questionnaire scores

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group receives lessons on Kegel training with the biofeedback technique by a physiotherapist during a one-hour training session, and they are also given a home exercise schedule. For one month, these patients will do the exercises at home each day. Patients undergo radical prostatectomy, and standardized postoperative approaches will be considered for them until discharge. Then the control group will continue these exercises within six months (after the removal of their urinary catheter the day after the operation until the sixth month after the removal of their catheter).

Category
Rehabilitation

2

Description
The control group would undergo radical prostatectomy, and standardized postoperative approaches will be considered for them until discharge, but they receive no intervention.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Noor hospital

Full name of responsible person
Mohammad Hatef Khorrami

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Noor hospital, Ostandary Ave., Hasht Behesht Blvd., Isfahan, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mohammad Hatef Khorrami

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Urology

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
The data of the participants, which includes demographic data and the primary outcome variables of the study, exists in data files that can be shared after individuals were unidentified.

When the data will become available and for how long
Data will be available from March 2021.

To whom data/document is available
Researchers working in universities or scientific institutions

Under which criteria data/document could be used
The data will be available for more advanced statistical analysis and review with the official permission of the Vice-Chancellor of Research of Isfahan University of Medical Sciences.

From where data/document is obtainable
To obtain official permission to access the data, the applicant must refer to the Office of the Vice-Chancellor of Research of Isfahan University of Medical Sciences in Isfahan, Iran.

What processes are involved for a request to access data/document
First, the applicant will apply for access to the data by referring to the Office of the Vice-Chancellor of Research of Isfahan University of Medical Sciences. Then the request will be processed by the Vice-Chancellor of the Isfahan University of Medical Sciences and, if deemed appropriate, the applicant will be allowed access to the information. In the next step, the applicant refers to the Research Office of the University and the data will be provided to him/her. This process may take a period of one to two months.

Comments