

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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)

##### Phone

+98 31 3668 6444

##### Email address

admin.ycc@med.mui.ac.ir

##### 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

## 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

Isfahan

##### 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

#### Street address

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

#### City

Isfahan

#### Province

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#### Postal code

8155684845

#### Phone

+98 31 3220 8081

#### Email

Shekayat.nour@gmail.com

#### Web page address

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Shaghayegh Haghjoo Javanmard

#### Street address

Isfahan University of Medical Sciences, Hezar Jarib

Ave., Isfahan, Iran.

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#### Province

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#### Phone

+98 31 3668 8138

#### Email

sh\_haghjoo@med.mui.ac.ir

#### 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

#### Street address

Urology department, Al-Zahra hospital, Soffe Blvd., Isfahan, Iran.

#### City

Isfahan

#### Province

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#### Postal code

8174675731

#### Phone

+98 31 3668 5555

#### Email

kharami386@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amir Mohseni

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Urology

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+98 31 3668 5555

**Email**

due\_prosperity@yahoo.com

## 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