

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the Effect of Pelvic Floor Muscle Biofeedback prior or post Radical Prostatectomy on Urinary Incontinence: A Randomized Clinical Trial

Protocol summary

Study aim

To determine whether biofeedback-based PFMT prior or after radical prostatectomy could result in early achievement of continence.

Design

In this single- blinded randomized control trial with control group, 58 subjects enrolled in the study. patients randomized in to three groups. In the two case groups, biofeedback will perform before or after surgery.

Settings and conduct

All patients with the definitive diagnosis of prostate cancer who are referred to Shohada-e-Tajrish Hospital will enroll in the study. In this single blinded study, patients will be blinded by using functional biofeedback probe in the case groups whereas the control group receives nonfunctional probes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with prostate cancer confirmed by TRUSBx who are eligible for radical prostatectomy Exclusion criteria: patients who were diagnosed with prostate cancer following Transurethral Resection of Prostate, patients who received pelvic radiotherapy regardless of their primary malignancy, spinal cord injury, comorbidities that can affect urinary continence , history of pelvic or retroperitoneal surgery, neurologic disorders.

Intervention groups

In the first group, biofeedback was performed for pelvic floor muscles by a physiatrist for the duration of 30 minutes, 2 times a week for a duration of 2 weeks prior to surgery. In the second group no intervention carried out before surgery, but after removing Foley catheter, patients underwent pelvic muscle biofeedback by a physiatrist for a duration of 30 minutes, 2 times a week for 2 weeks. And finally in the third group, probe without any function will plaaced on patients' perineum.

Main outcome variables

biofeedback before radical prostatectomy on urinary incontinence after surgery according to King's Health Questionnaire before surgery and in 1,3 and 6 months after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200429047243N1**

Registration date: **2020-05-05, 1399/02/16**

Registration timing: **retrospective**

Last update: **2020-05-05, 1399/02/16**

Update count: **0**

Registration date

2020-05-05, 1399/02/16

Registrant information

Name

saeed montazeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8006

Email address

saeed.montazeri89@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

2019-09-23, 1398/07/01
Actual recruitment end date
2020-04-20, 1399/02/01
Trial completion date
2020-07-22, 1399/05/01

Scientific title

Comparison the Effect of Pelvic Floor Muscle Biofeedback prior or post Radical Prostatectomy on Urinary Incontinence: A Randomized Clinical Trial

Public title

Comparison the Effect of Pelvic Floor Muscle Biofeedback prior or post Radical Prostatectomy on Urinary Incontinence

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Men with prostate cancer confirmed with TRUSBx who are candidates for radical prostatectomy

Exclusion criteria:

patients who were diagnosed with prostate cancer following Transurethral Resection of Prostate patients who received pelvic radiotherapy regardless of their primary malignancy spinal cord injury comorbidities that can affect urinary continence (such as: diabetes mellitus, overactive bladder, urethral stricture, etc.) history of pelvic or retroperitoneal surgery neurologic disorders (e.g.: Multiple Sclerosis, seizures, etc.)

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Actual sample size reached: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized in to three groups by a randomization software and then sealed envelope. simple randomization and individual randomization applied. Sequentially numbered, sealed, opaque envelopes will use for allocation concealment.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single blinded study, patients will be blinded by using functional biofeedback probe in the case groups whereas the control group receives nonfunctional probes.

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

urology and nephrology research center

Street address

pasdaran street, boustan 9th, between eslami and paydarfard street

City

tehran

Province

Tehran

Postal code

1666677951

Approval date

2018-08-11, 1397/05/20

Ethics committee reference number

IR.sbm.unrc.rec.1397.20

Health conditions studied

1

Description of health condition studied

Neuromuscular dysfunction of bladder, unspecified

ICD-10 code

N31.9

ICD-10 code description

Neuromuscular dysfunction of bladder, unspecified , prostate cancer

Primary outcomes

1

Description

biofeedback before radical prostatectomy on urinary incontinence after surgery according to King's Health Questionnaire

Timepoint

before surgery and 1,3 and 6 months after surgery

Method of measurement

King's Health Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: biofeedback prior to radical prostatectomy

Category

Rehabilitation

2

Description

Intervention group: biofeedback after radical prostatectomy

Category

Rehabilitation

3

Description

Control group: no biofeedback

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye tajrish hospital

Full name of responsible person

Saeed Monntazeri

Street address

Tehran Province, Tehran, District 1, tajrish square, shohadaye tajrish hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Tehran Province, Tehran, Velenjak, 7th Floor, Bldg No.2 SBUMS, Arabi Ave

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeed Montazeri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

urology resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

only a fraction of data consisting of primary outcome will be shared.

When the data will become available and for how long

data will become available three months after publication.

To whom data/document is available

only people working in academic institutions will have access to these data.

Under which criteria data/document could be used

further statistical analysis on the data is permitted.

From where data/document is obtainable

applicants can contact us on E-mail: saeed.montazeri89@gmail.com

What processes are involved for a request to access data/document

After consultation with other researchers, decision will be made for data sharing. this procedure should not take more than two months.

Comments

No comment