

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The evaluation of an integrated physical therapy protocol on male stress urinary incontinence after radical prostatectomy

Protocol summary

Study aim

Determine the effect of integrated therapy on male stress urinary incontinence secondary to radical prostatectomy.

Design

Double blinded randomized control trial with three parallel group, with 60 patient. Randomization was done by a random number generator.

Settings and conduct

All groups receive 12 session of treatment in one month (3 session every week). this treatment sessions would be conducted in rehabilitation clinic of Shahid Beheshti rehabilitation school. Also for electrotherapy an interferential 520 p plus device would be use which is produced by novin company in iran in 2020. integrated therapy group receive a treatment that include electrotherapy (interferential therapy that electrodes would be place at lower abdomen and inner thigh), manual therapy (neuromuscular therapy for diaphragm and iliopsoas muscles) and exercise therapy (pelvic floor and breathing exercise). pelvic floor exercise group receive only education and guidance for pelvic floor muscle exercise and monitoring for this exercise. Control group receive sham electrotherapy (pad placement similar to integrated therapy group but without any current.)

Participants/Inclusion and exclusion criteria

The participant include males with stress urinary incontinence diagnosed by urologist ranging from 50-80 years old. Also exclusion criteria would be any major orthopedic or neurological problems.

Intervention groups

Integrated therapy group: this group treatment include: electrotherapy, manual therapy and exercise therapy
Pelvic floor muscle exercise group: this group only received training and monitoring in Pelvic floor muscle exercises. Control group: This group only received sham electrotherapy (pad placement would be done but no current)

Main outcome variables

Including incontinence parameters (urinary/incontinence episodes , urination and fluid intake amount) : Quality of life (SF12)

General information

Reason for update

Acronym

SUI

IRCT registration information

IRCT registration number: **IRCT20151028024751N1**

Registration date: **2021-08-17, 1400/05/26**

Registration timing: **prospective**

Last update: **2021-08-17, 1400/05/26**

Update count: **0**

Registration date

2021-08-17, 1400/05/26

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 77576268

Email address

okhovatianf@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-07, 1400/07/15

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of an integrated physical therapy protocol on male stress urinary incontinence after radical prostatectomy

Public title

Male stress urinary incontinence after radical prostatectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Stress urinary incontinence secondary to radical prostatectomy surgery diagnosed by urologist Age between 50 to 80

Exclusion criteria:

Major neurological problems such as Parkinson, Multiple sclerosis and central nervous system anomalies Major orthopedic problems in spine and pelvic Using duloxetine or similar drugs that have a similar effect on incontinence Uncontrolled diabetes or other peripheral nerve system diseases that cause sensation problem Any pervious rehabilitation treatment for incontinence after last surgery Skin inflammation, thrombosis or pacemaker

Age

From **50 years** old to **80 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient divided into three random group by a random number generator. the process would be done for every person and by simple randomization process. To randomize participants their names will be inserted into the Excel application. Then by using rand function a random number will be assigned to every participant. Then this number will be sort by application from the highest to lowest that this action will disorient the list and randomize participants placement in list. Then first 20 participants in list will be in integrated therapy group and second 20 participants in list will be in pelvic floor muscle exercise group and last 20 participants in list will be in control group. Randomize process will be done by statistics Advisor and groups will be assigned base on number 1 for integrated therapy group , number 2 for pelvic floor muscle group exercise and number 3 control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participated patients would not know that if they are in the treatment groups or control group. Control group would receive sham electrotherapy without any current. Analyzer receive patients group detail by number 1-3 and would not know about groups situation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of shahid Beheshti university of medical sciences

Street address

7th Floor, Bldg No.2 SBUM, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran

City

تهران

Province

Tehran

Postal code

1985717443

Approval date

2021-03-09, 1399/12/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1317

Health conditions studied**1****Description of health condition studied**

Male urinary stress incontinence

ICD-10 code

R32

ICD-10 code description

Unspecified urinary incontinence

Primary outcomes**1****Description**

incontinence episode

Timepoint

daily

Method of measurement

bladder diary questionnaire

2

Description

quality of life

Timepoint

monthly

Method of measurement

SF12 questionnaire

3

Description

urination frequency

Timepoint

daily

Method of measurement

bladder diary questioner

4

Description

Fluid intake

Timepoint

daily

Method of measurement

Calibrated container

5

Description

Urination amount

Timepoint

daily

Method of measurement

Calibrated container

Secondary outcomes

empty

Intervention groups

1

Description

Control group: control group (sham electrotherapy) For this group sham electrotherapy will be done for 12 sessions in 4 weeks. Electrodes will be placed at lower abdominal (above inguinal ligament) and higher one third of thigh in the medial side but no current would be applied to them. after the data collection at the end of the study the approach that had the best outcome (pelvic floor muscle exercise or integrated therapy) will be done for this group too.

Category

Placebo

2

Description

Intervention group: integrated therapy . For this group 12 session of integrated therapy will be done in 4 weeks. In this treatment electrotherapy will be done first with

interferential current that electrodes will be placed at lower abdominal (above inguinal ligament) and higher one third of thigh in the medial side and 0-100 Hz frequency for 15 minutes. An interferential 520 p plus model 2020 made in Iran will be used to apply this current. Then manual therapy (neuromuscular therapy technique) will be done for iliopsoas and diaphragm muscles. Then exercise therapy for diaphragmatic breathing exercise, Knack exercise, Kegel exercise and pelvic floor muscles synergies exercise (gluteus maximus and medius , multifidus and abdominal muscles) will be done. In the first session these exercises will be taught to patient then in the later sessions patient exaction of this exercises will be monitored by therapist. Sets , number and intensity of this exercises for home will be instruct based on patient status by therapist. Also, an instruction manual will be provided to patient for this exercises to this exercises correctly.

Category

Rehabilitation

3

Description

Intervention group: Pelvic floor muscle exercises. For this group 12 session of exercise therapy for Knack exercise, Kegel exercise and pelvic floor muscles synergies exercise (gluteus maximus and medius , multifidus and abdominal muscles) will be done in 4 weeks. In the first session these exercises will be taught to patient then in the later sessions patient exaction of this exercises will be monitored by therapist. Sets , number and intensity of this exercises for home will be instruct based on patient status by therapist. Also, an instruction manual will be provided to patient for this exercises to this exercises correctly

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rehabilitation Faculty of SBMU

Full name of responsible person

Mohammad Sheibani far

Street address

Rehab Faculty, Damavan Str, Immam Hossein Square

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7754 2057

Email

tavan2020@yahoo.com

Web page address

<http://rehab.sbm.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sedigheh Naimi

Street address

Rehab Faculty, Damavand Str, Immam hossein square

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Postal code

1616913111

Phone

+98 21 7754 2057

Email

tavan2020@yahoo.com

Web page address

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

Farshad Okhovatian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Damavand street, across from Buali hospital, Tehran, Iran. SBMU School of Rehabilitation Sciences.

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Phone

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Email

okhovatianf@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

Contact

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All of this study data could be shared after making it

unrecognizable.

When the data will become available and for how long

Data would be shared one month after publication.

To whom data/document is available

This data only assessable for academic researchers.

Under which criteria data/document could be used

There is no specific qualification for using this study data.

From where data/document is obtainable

To receive this study data please contact Dr.Farshad

Okhovatian. phone:00982177561721

fax:00982177561721 email:okhovatianf@sbmu.ac.ir

address: Damavand street, across from Buali hospital,

Tehran, Iran. SBMU School of Rehabilitation Sciences.

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

Only a request letter would be enough for receiving data.

Comments