Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 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 incomitance 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
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1616913111
Phone
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Email
tavan2020@yahoo.com
Web page address
http://rehab.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sedigheh Naimi
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Rehab Faculty, Damavand Str, Immam hossein square
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Email
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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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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
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