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Efficacy of physiotherapy in post-prostatectomy urinary incontinence

Submission date
11/01/2017

Recruitment status
No longer recruiting

Registration date
13/01/2017

Overall study status
Completed

Last Edited
18/01/2017

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
A radical prostatectomy is an operation to remove the prostate gland in order to remove prostate cancer. The most common side effects of the operation are unintentional passing of urine (urinary incontinence) and problems with getting and keeping an erection (erectile dysfunction). This greatly reduces the patient's quality of life. The aim of this study is to test a physiotherapy program for urinary incontinence three months after radical prostatectomy.

Who can participate?
Men aged over 18 who have undergone a radical prostatectomy and are experiencing incontinence and erectile dysfunction

What does the study involve?
Participants are randomly allocated to one of two groups. One group is treated with biofeedback pelvic floor training, a type of physical therapy that trains the brain and pelvic muscles to work together to tighten and relax the pelvic floor muscles. An anal electrode is used to record the activity of the pelvic floor muscles for 30 minutes. The patients also receive electrical stimulation for 15 minutes. The treatment lasts 45 minutes per day, 3 days per week. At home, patients also train their pelvic muscles through Kegel exercises throughout the day. The other group is treated according to the usual clinical practice, and an information sheet with Kegel exercises is provided after the operation. Both groups are assessed for incontinence, erectile dysfunction and quality of life at the start of the study and after 1 month, 2 months, 3 months (end of treatment), 6 months and 12 months.

What are the possible benefits and risks of participating?
The study will show whether physiotherapy can be used to treat urinary incontinence after prostatectomy. There is currently no standard treatment for this. Participants may benefit from an improvement in their urinary incontinence symptoms. The physiotherapy has no adverse effects. Sometimes it can cause discomfort due to the electrode being in the wrong position, but it can be fixed by adjusting the position of the electrode.

Where is the study run from?
Clínica Mercedes Soto (Spain)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Mercedes Soto-González
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016

Study information

Scientific Title
Effectiveness of a physiotherapy program in the treatment of urinary incontinence post-prostatectomy: a randomized controlled trial

Study objectives
The physical therapy program will improve the urinary incontinence in post-prostatectomy patients in three months.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Pontevedra-Vigo-Ourense Research Ethics Committee of the Health Department, 05/11/2014, ref: 2014/351

Study design
Interventional single-centre randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Post-prostatectomy urinary incontinence

Interventions
Participants are assigned to the control group or intervention group through simple randomization. Doctors, patients and evaluators will not be blinded.

1. Intervention: Biofeedback is used for the pelvic floor training. An anal electrode records the activity of the pelvic floor muscles (30 minutes). Besides, the patients receive electrostimulation during 15 minutes. The treatment (biofeedback + electrostimulation) is 45 minutes per day (3 days per week). At home, patients train their pelvic muscles through Kegel exercises throughout the day.
2. Control: usual clinical practice. An information sheet with Kegel exercises is provided after the operation.

Patients are assessed at baseline, 1 month, 2 months, 3 months (end of treatment), 6 months and 12 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Loss of urine, measured using the 24 h Pad test and 1 h Pad test, at baseline, 1 month, 2 months, 3 months (end of treatment), 6 months and 12 months

Secondary outcome measures

1. Quality of life and incontinence, measured using the ICIQ-SF questionnaire at baseline, 1 month, 2 months, 3 months (end of treatment), 6 months and 12 months
2. Erectile dysfunction, measured using the International Index of Erectile Function (IIEF-5) at baseline, 1 month, 2 months, 3 months (end of treatment), 6 months and 12 months
3. Life habits, measured using a urinary diary at baseline, 1 month, 2 months, 3 months (end of treatment), 6 months and 12 months

Overall study start date
01/01/2015

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Male patients intervened with radical prostatectomy
2. Incontinence (any loss of urine)
3. Erectile dysfunction, defined as a score under 21 in the International Index of Erectile Function (IIEF-5)
4. Over 18 years old

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
134 patients (67 patients in each group)

Key exclusion criteria
1. Patients with neurological pathology (advanced Parkinson's, multiple sclerosis and disease with deterioration of cognitive or sensitive capacities or that course with muscle weakness)
2. Patients with serious disease processes such cancer, severe epoc, severe pulmonary hypertension
3. Patients with a pacemaker
4. Patients taking muscle relaxing medication
5. Patients with incotinence or erectile dysfunction with a score under 7 in the questionnaire IIEF-5 previous to the intervention

Date of first enrolment
15/02/2015

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Spain

Study participating centre
Clínica Mercedes Soto
Emilia Pardo Bazán 29 Bajo
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Sponsor information

Organisation
University of Vigo

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Sponsor type
University/education

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ROR
https://ror.org/05rdf8595

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Mercedes Soto-González (m.soto@uvigo.es)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		12/01/2017	18/01/2017	No	Yes