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What causes incontinence after robot-assisted prostate removal in men with prostate cancer?

Submission date 03/12/2018	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 01/05/2019	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 02/10/2024	**Condition category** Surgery	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Prostate cancer is a very common disease and the complete removal of the prostate, radical prostatectomy (RP), is Gold Standard for treating localized disease with 3000 procedures/year in Sweden alone. Robot assisted laparoscopic RP (RALP) constitutes a large and growing part. RALP can cause a number of complications of which urinary incontinence has the largest impact of quality of life (QoL) affecting about 1/5 of the patients. We have identified risk factors for incontinence by analyzing 3000 RALP patients and also also by reviewing a number of films from 800 procedures performed at Sahlgrenska University Hospital. We will use the results from these analyzes in this study study. The aim is to identify what is different in the procedure between a continent and an incontinent patient. We will also record all procedures for further analyses. As a side project we will also with MRT analyze how the prostatic bed changes during RALP to help minimize the field of radiation at potential post-op recurrent disease. To identify and positively affect the factors of the procedure that lead to incontinence would greatly affect a large number of both patients and their kin.

Who can participate?

Patients without pre-operative urinary leakage, planned for radical prostatectomy at Department of Urology, Sahlgrenska University Hospital between 1 Jan 2019 to 31 Dec 2020. The inclusion may be prolonged if accrual is too low.

What does the study involve?

A magnetic resonance tomography (MRT) of the prostate and pelvic floor, a transrectal ultrasound and a urodynamic assessment at the start of the study and at 12 weeks. The radical prostatectomy procedure is also video recorded.

What are the possible benefits and risks of participating?

There are no direct benefits for the participating men. As the investigations are clinical routine in many other conditions the risks for the participants are minimal.

Where is the study run from?

1. Department of Urology, Sahlgrenska University Hospital, Sahlgrenska Academy at University of Gothenburg. Sweden

2. Department of Urology, NU-sjukvården, Uddevalla Hospital, Sweden (added 21/01/2020)
3. Department of Urology, Carlanderska Hospital, Gothenburg, Sweden (added 21/01/2020)

When is the study starting and how long is it expected to run for?
January 2015 to December 2028

Who is funding the study?
1. The Swedish patient prostate cancer society
2. Percy Falks Foundation
3. ALFGBG 720421 VG-Region

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Grant ALFGBG-720421

Study information

Scientific Title
Incontinence post-robot-assisted radical prostatectomy: anatomical and functional causes

Acronym
IPA

Study objectives
This prospective, open-label, non-randomized observational trial seeks to investigate which aspects of robot-assisted radical retropubic prostatectomy leads to post-operative incontinence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional ethics review board of Gothenburg (Dnr 131-16), 24/03/2016, Dnr 131-16

Study design
Prospective open non-randomized observational trial

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Only in Swedish, not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Incontinence following radical prostatectomy for prostate cancer

Interventions
MRT, urodynamics and trans-rectal ultrasound pre-operative and at three months postoperative

The plan of study visits is described below.

VISIT 1
The assessment of eligibility is done by a urologist. After assessment of eligibility the patient is included and informed consent is signed.The patient will fill in the NPCR PROM-survey and will be scheduled for the urodynamic- and ultrasound-visit at the urological department. A referral for MRT of the prostate (T2) is sent to the radiological department to be performed within 30 days.

VISIT 2
To be performed within 30 days of inclusion. MRT (T2) at the radiological department.

VISIT 3
To be performed within 30 days of inclusion. Urodynamics is performed as routine. Dynamic transrectal ultrasound at the urological department.

VISIT 4
Surgery. Procedure is recorded on hard drive for later analysis.

VISIT 5
To be performed at three months after surgery (+/- 2 weeks). MRT at the radiological department.

VISIT 6
To be performed at three months after surgery (+/- 2 weeks). Urodynamics, dynamic transrectal /perineal ultrasound at the urological department. Patient answers continence questionnaire at the urological department.

Intervention Type
Other

Primary outcome measure
Urethral length, position of prostate apex, position of bladder neck, position of urethra, thickness of urethra, M. levator ani and M. Pubourethralis/puborectalis and signs of fibrosis of urethra wall, assessed by MRT at baseline and 12 weeks (except for prostate apex at 12 weeks)

Secondary outcome measures
1. Clinical characteristics (comorbidity, medications, BMI, smoking, IPSS, PSA, Gleason score and T-stage) assessed at baseline
2. Urethra pressure profile, sphincter length, function of bladder and bladder outflow tract assessed by urodynamics at baseline and 12 weeks
3. Position and movement of bladder neck and pelvic floor at relaxation and full tension of pelvic floor assessed by ultrasound at baseline and at 12 weeks.
4. Steps of surgery and potential damage of structures around sphincter assessed by video recording at time of surgery

Overall study start date
01/01/2015

Completion date
31/12/2028

Eligibility

Key inclusion criteria
Patients scheduled for robot-assisted laparoscopic radical prostatectomy at Sahlgrenska University Hospital

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
1000

Key exclusion criteria
Pre-operative incontinence

Date of first enrolment
01/01/2018

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Sweden

Study participating centre
Sahlgrenska University Hospital
Dept. of Urology
Bruna Stråket 11B
Gothenburg
Sweden
41645

Study participating centre
Uddevalla Hospital
Dept. of Urology
NU-sjukvården
Fjällvägen 9
Uddevalla
Sweden
SE-451 53

Study participating centre
Skåne University Hospital
Malmö
Sweden
-

Study participating centre
Karolinska Stockholm
Stockholm
Sweden
-

Study participating centre
Skövde Hospital
Skövde
Sweden
-

Sponsor information

Organisation
University of Gothenburg

Sponsor details
Box 100
Gothenburg
Sweden
40530

Sponsor type
University/education

Website
https://www.gu.se

ROR
https://ror.org/01tm6cn81

Funder(s)

Funder type
Other

Funder Name
ALF-medel Västra Götaland

Funder Name
Prostatacancerförbundet (Swedish Prostate Cancer Association)

Funder Name
Percy Falks Stiftelse för Forskning Beträffande Prostata- och Bröstcancer

Alternative Name(s)
Percy Falks Stiftelse

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

Publication and dissemination plan
Results on causes for post-operative incontinence will be reported in peer-reviewed journal as soon as accrual is complete and data has been analysed.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		30/09/2024	02/10/2024	Yes	No