

Dynamics of male pelvic floor contractions through transperineal ultrasound imaging in continent and incontinent patients after radical prostatectomy.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23686

Source

NTR

Brief title

N/A

Health condition

Urinary incontinence

Radical prostatectomy

Transperineal ultrasound

Sponsors and support

Primary sponsor: KU Leuven, Faculty of Kinesiology and Rehabilitation Science

Source(s) of monetary or material Support: Institute for the Promotion of Innovation by Science and Technology in Flanders (IWT), Toegepast Biomedisch onderzoek met een primaire Maatschappelijke finaliteit (TBM)

Intervention

Outcome measures

Primary outcome

To investigate if the displacement of the anorectal junction, ventral and dorsal urethrovesical junction, dorsal point of the bulbus and dorsal point of the striated urethral sphincter have a good intra- and interrater reliability.

Secondary outcome

To compare the displacement of the different structures of urinary continent and incontinent men after radical prostatectomy.

Study description

Background summary

Prostate cancer is the most common cancer in men on this moment. Radical prostatectomy is since many years the gold standard for eradication of localized prostate cancer. Urinary incontinence however remains one of the most embarrassing complications after prostatectomy. This project aims to investigate the underlying causes of urinary incontinence by visualising the displacement of several points along the urethra, while contracting the pelvic floor, with transperineal ultrasound.

Study objective

1. To investigate the intra- and interreliability of transperineal ultrasound measurements of the displacement of multiple points along the urethra in men after radical prostatectomy;
2. To compare the relative displacement of urethrovesical junction, anorectal junction and distal urethra during voluntary pelvic floor muscle contractions from preoperative to 3 months postoperative after radical prostatectomy;
3. To compare the relative displacement of urethrovesical junction, anorectal junction and distal urethra during voluntary pelvic floor muscle contractions between continent and incontinent men after radical prostatectomy.

Study design

Group 1 (continent men): Preoperatively and 3 months postoperatively;

Group 2 (incontinent men): Minimum 1 year postoperatively.

Intervention

Both groups will have transperineal ultrasound.

Group 1: Patients who are planned for a radical prostatectomy will have a transperineal ultrasound of the displacement of multiple points along the urethra pre- and postoperatively.

Group 2: Patients who had a radical prostatectomy minimum one year before and are still incontinent will have a transperineal ultrasound of the displacement of the same multiple points along the urethra.

Contacts

Public

Postbus 1501
Inge Geraerts
Katholieke Universiteit Leuven
Faculteit Bewegings- en Revalidatiewetenschappen
Tervuursevest 101
Leuven 3001
Belgium
+32 16329120

Scientific

Postbus 1501
Inge Geraerts
Katholieke Universiteit Leuven
Faculteit Bewegings- en Revalidatiewetenschappen
Tervuursevest 101
Leuven 3001
Belgium
+32 16329120

Eligibility criteria

Inclusion criteria

Continent patients:

1. Patients who will have a radical prostatectomy for localised or locally advanced prostate

cancer in the University Hospital Gasthuisberg in Leuven;

2. Patients who can participate in one pre- and one postoperative transperineal ultrasound measurement in the University Hospital Gasthuisberg.

Incontinent patients:

1. Patients who had a radical prostatectomy in the University Hospital Gasthuisberg, minimally 1 year before and are still urinary incontinent;

2. Patients willing to participate in one transperineal ultrasound measurement.

Exclusion criteria

Patients who don't want to participate to the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2012
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date: 24-10-2012

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3516
NTR-old	NTR3678
Other	IWT : 080678
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A