

# Functional effects of treatment of organ confined prostate cancer on lower urinary tract

Published: 04-12-2007

Last updated: 10-08-2024

1-objective: to get insight in objective (urodynamic) and subjective (questionnaire) changes of the lower urinary tract after laparoscopic robot assisted radical prostatectomy, Intensity modulated radiotherapy, I-125 brachytherapy.2-To create...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bladder and bladder neck disorders (excl calculi)
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON33683

### Source

ToetsingOnline

### Brief title

urodynamics in prostate cancer treatment

### Condition

- Bladder and bladder neck disorders (excl calculi)

### Synonym

urinary urgency /urinary leak

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Brachytherapy/IMRT/complications/urodynamic effects

## Outcome measures

### Primary outcome

Urodynamic changes in comparison with the baseline:

- Maximum flow rate
- Volume of the first muscle instability.
- Amplitude of the first instable contraction
- Amplitude of the maximal instable contraction
- Volume of the maximal instable contraction
- Volume of the first desire to urinate
- Bladder compliance before and after brachytherapie
- Maximale urethral closure pressure (MUCP)
- Urethrale pressure profile-length
- Urethrale resistance/URA\_BOOI
- Schafer graad
- Bladder contractility index:  $PQ_{max} + 5 \times Q_{max}$ ,  $W_{max}$ ,  $WQ_{max}$
- \* Post-void residue
- \* 24 uur padtest

### Secondary outcome

The subjective changes of parameters in comparison with the baseline:

## International Prostate Symptom Score (IPSS)

- Frequentie- volume Chart
- EPIC-MICTURATION
- EPIC-INTESTINAL SYMPTOMS
- EPIC-SEXUALITY

## Study description

### Background summary

The treatment of organ confined prostate cancer is radical prostatectomy/external beam radiotherapy or I-125 brachytherapy. In umc utrecht we offer Laparoscopic robot assisted radical prostatectomy, Intensity modulated radiotherapy, I-125 brachytherapy.

Each modality has its own complication profile.

The objective effects of these modalities have never prospectively been studied. The complication profile of each modality plays an important role in the therapy decision making process. The choice of therapeutic modality is often based on guidelines and less based on evidence in the literature.

This research makes it possible (Theoretically) to recognize the patient at risk of complication. To create a selection criteria and to tailored an adequate treatment for the patient with locally confined prostate cancer a prospective study on the (objective and subjective) effects of each therapy on urinary tract is a justified.

### Study objective

1-objective: to get insight in objective (urodynamic) and subjective (questionnaire) changes of the lower urinary tract after laparoscopic robot assisted radical prostatectomy, Intensity modulated radiotherapy, I-125 brachytherapy.

2-To create selection criteria to tailored an adequate treatment option for the patient with locally confined prostate cancer.

### Study design

An observational, prospective cohort research on functional effects of different therapeutic modalities of locally confined prostate cancer on lower

urinary tract.

### **Study burden and risks**

Urodynamic study of the lower urinary tract is fairly comparable with inserting catheter. It may result in lower urinary tract infection. This may occur in 2% of patients undergoing this test. To reduce the chance of infection, the patients with high risk will be prophylactically treated with antibiotics.

## **Contacts**

### **Public**

Universitair Medisch Centrum Utrecht

Heidelberglaan 100

3584 CX

Nederland

### **Scientific**

Universitair Medisch Centrum Utrecht

Heidelberglaan 100

3584 CX

Nederland

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

Proven organ confined prostate cancer with indication for curative treatment

## Exclusion criteria

(locally) advanced prostaat carcinoom

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 05-11-2008

Enrollment: 120

Type: Actual

## Ethics review

Approved WMO

Date: 04-12-2007

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date: 02-02-2010

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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**

<b>Register</b>	<b>ID</b>
CCMO	NL17075.041.07