A clinical pathway for older prostate cancer patients

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON40972

Source
ToetsingOnline

Brief title
Clinical Pathway Prostate Cancer

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
malignancy of the prostate, Prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: NIVEL
Source(s) of monetary or material Support: KWF Kankerbestrijding,REshape & Innovation centre van het Radboudumc

Intervention

Keyword: clinical pathway, primary care, prostate cancer

Outcome measures

Primary outcome

The primary outcome measure of this project is the existence of a succesful clinical pathway for older prostate cancer patients. This will be assessed by the following criteria:

- GPs do not refer patients to the urologist (unless for recurrence/metastasis).
- The majority of the patients is satisfied
- The participating GPs and urologists are convinced and confident

Secondary outcome

perceived quality of care and prostate cancer specific quality of life, health care use and satisfaction with videoconsultations

Study description

Background summary

Half of the patients who have been diagnosed with prostate cancer is over 70 years and many patients suffer from other chronic diseases in addition to prostate cancer. The treatment of prostate cancer can be influenced by these additional diseases and vice versa. Also, several different care providers will be involved in the care for elderly patients with complex care needs. Therefore, a patient-centred approach that goes beyond the disease is needed.

It could turn out to be positive when GPs are more involved in the after-care for prostate cancer. The GP has, as generalist a good overall picture of the complete medical and psycho-social situation of the patient. Many patients see their GP already regularly and care needs might be combined within one consultation. Patient do not have to travel far. It is also advantageous for

the GP that he has a more complete picture of the health situation of the patient and it could save money.

Shifting the complete after-care to the GP might not be possible and not desirable, because specific oncological expertise is needed. Teleconsultation might be the solution. The specialist can be virtually present at a GP consultation in videoconsultation, and vice versa. The result is streamlined multidisciplinary care with the real focus on the patient. This way, multi-agency cooperation, patient participation and patient satisfaction can be improved. In addition, the GP extends his oncological knowledge.

Study objective

The objective of the study is to dimplement and evaluate a new care path for elderly prostate cancer patients with complex care needs within 20 months. This will be done withinthe department of urology at the Meander Medisch Centrum at Amersfoort, in cooperation with several GP practices in the Amersfoort region.

Study design

In the clinical pathway, the care for the patients in the after-care phase will be shifted from specialist to GP, supported by videoconsultation with urologists or geriatrician, where needed.

At the start of the project, the participating GPs and urologists have jointly developed a treatment protocol for the after-care of prostate cancer for GPs. This will be implemented at the Meander MC and several GP practices in the Amersfoort region . When patient and GP agree, patients with prostate cancer in these practices will receive after-care during 12 months according to the clinical pathway.

At the end of the project interviews will be conducted with the participating patients, GPs and specialists, about their experiences. For every patient who joins the project, the quality of care from the perspective of the patient and prostate cancer specific quality of life will be measured before the after-care and after a year. Care use will be extracted from the patient information system of the GP and the Meander MC. Also, the patients will be asked for their care use in other hospitals after 6 and 12 months.

Study burden and risks

Burden and risks associated with participation are low. Patient are asked to fill out a questionnaire at the start of the study and after 6 months, taking approximately 10 minutes, and the end of the study, taking approximately 30 minutes. Besides they are asked to be interviewed by one of the researchers,

which will take approximately 30 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Diagnosis of prostate cancer
• Age at least 65 and at least one chronic disease (of a list of 30 diseases of the RIVM);Specific criteria for the different treatment options:
After radical prostatectomy inclusion 1 year after operation if:
• PSA < 0,1
• No other active treatment by urologist (for example erectile dysfunction or incontinence)
After radiotherapy (in- or external) inclusion 1 year after radiotherapy if:

• PSA declining
• No other active treatment by urologist (for example erectile dysfunction or incontinence)
Watchful waiting inclusion 6 months after start watchful waiting if:
• PSA stable
• No other active treatment by urologist (for example erectile dysfunction or incontinence)
Hormone therapy inclusion 6 months after start hormone therapy if:
• Health complaints absent or stable

Exclusion criteria

- In active medical treatment
- After-care by GP not medically safe
- in the normal situation the patient would be checked by the urologist for at least one year

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-10-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	22-07-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	27-08-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	05-12-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL47835.100.14