PROSPEC study; PROstate cancer follow-up care in Secondary and Primary hEalth Care

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We hypothesize that the follow-up and aftercare of prostate cancer in the Netherlands can be led by the GP. We hypothesize that GP-led recurrence detection programme leads to at least equal detection of recurrences as the current follow-up in...

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON48798

Source
ToetsingOnline

Brief title
PROSPEC study

Condition

- Reproductive neoplasms male malignant and unspecified
- Genitourinary tract disorders NEC

Synonym
prostate cancer, prostatic adenocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: KWF

Intervention

Keyword: follow-up, primary care, prostate cancer, survivorship care

Outcome measures

Primary outcome

Primary outcome is the effect of GP-based versus specialist-based follow-up care on adherence to the prostate cancer surveillance guideline.

Secondary outcome

Secondary outcomes include the time from a biochemical recurrence (BCR) to prostate cancer retreatment decision-making in an interdisciplinary setting, management of treatment-related side effects and comorbidities, health promotion recommendations, prostate-cancer related anxiety and quality of life, continuity of care, and cost-effectiveness.

Study description

Background summary

Prostate cancer is the most common cancer in men in the Netherlands. In 2017, 11.000 men were diagnosed with prostate cancer. Approximately 80% of the men are diagnosed with local or regional prostate cancer (the tumour is not extended outside the prostate). Common treatments for men with localized prostate cancer (T1c - cT3 N0M0) are a radical prostatectomy or radiotherapy. Currently, in the Netherlands after initial treatment patients are included in a specialist-based programme (at the specialist who performed the primary treatment) where the principal elements of routine follow-up care are periodic visits for history-taking and physical examination, and surveillance by testing the prostate specific antigen (PSA). After primary treatment many prostate cancer survivors experience late effects of treatment, including urinary and bowel symptoms, sexual dysfunction, and adverse psychosocial and relationship effects. Illness related uncertainty, including PSA anxiety, has also been observed in a significant percentage of prostate cancer survivors.
To date, many publications indicate the need for improving the quality of survivorship care. several studies have shown an increase in the use of primary

health care (PHC) among cancer survivors in comparison to patients without a history of cancer. Although general practitioners (GPs) are often involved in cancer survivorship, they have not played a formal role in prostate cancer follow-up care. With the increasing number prostate cancer survivors, and with the many competing demands on cancer specialists* time and resources, the need to find alternative solutions for providing survivorship care for cancer patients cannot be overstated. Although several studies suggest that GPs might effectively take on the role of providing survivorship care to cancer survivors, there is little empirical evidence available on optimising and moving the focus of cancer follow-up from secondary to primary care.

Study objective

We hypothesize that the follow-up and aftercare of prostate cancer in the Netherlands can be led by the GP. We hypothesize that GP-led recurrence detection programme leads to at least equal detection of recurrences as the current follow-up in secondary care. Furthermore, we expect that better involvement of the GP will result in higher quality of life, better continuity of care, better preventative healthcare and counseling, and lower healthcare costs. If demonstrated to be equal to or better than specialist-led follow-up care, the possibility of providing GP-led prostate cancer survivorship care will be a welcome solution for the growing problem of providing appropriate follow-up services to the ever growing population of cancer survivors.

Study design

Multi-centre randomized controlled trial with a calculated total sample size of 390 patients. At the first follow-up visit at the hospital post-treatment, men will be invited by their treating specialist to participate in the study. Consenting patients will be randomized to GP-based or specialist-based (both consisting of 195 patients) follow-up care. All patients will be followed during a 2-year study period or until the development of a new primary cancer.

Intervention

GP-based follow-up and aftercare for prostatecancer survivors

Study burden and risks

In both study groups (experiment and control group) the national guideline for follow-up of prostate cancer will be used. It is hypothesized that the adherence to the prostate cancer surveillance guideline will not differ significantly between GP-led and specialist-led survivorship care. Furthermore, we expect that better involvement of the GP will result in higher quality of life, better continuity of care, better preventative healthcare and counseling, and lower healthcare costs. In order to reduce possible risks,

information will be given to the GP about primary treatment, any complications, subsequent treatment-related side effects, risk of recurrence, signs and symptoms of recurrence and recommended steps and procedures in the case of suspicion of recurrence. Also, an independent safety committee will evaluate the primary and main secondary endpoint twice, after 50 and 150 patients have finished the first three months of the intervention. In addition, all involved physicians will be asked by the primary researcher to report any potential adverse events caused by following the study protocol.
Finally, patients have to complete four questionnaires during the 2-year study period. The questionnaires take about 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

- Men diagnosed with invasive prostate cancer;
- Stage cT1a - cT3; pNx - pN1; R0-1 having completed primary treatment (prostatectomy or radiotherapy);
- Radiotherapy with or without androgen deprivation therapy (ADT) for localized prostate cancer
- No evidence of recurrence (PSA<0.1 ng/ml after prostatectomy or PSA< nadir+2.0 ng/mL after radiotherapy).

Exclusion criteria

- Primary treatment (prostatectomy, radiotherapy) completed longer than 6 months previously;
- Patients under active surveillance;
- Under investigation for possible recurrence (patients become eligible if recurrence is ruled out);
- Does not have a community-based GP to provide care;
- Unable to comply with study protocol including completion of questionnaires;
- Actively followed by a cancer specialist for another primary cancer;
- (Previously) enrolled in a study requiring ongoing follow-up by a cancer specialist;
- Serious (treatment related) toxicity that requires treatment;
- Patients that cannot sign informed consent or are unable to understand Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2018
Enrollment:	390
Type:	Anticipated

Ethics review

Approved WMO Date:	04-04-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-05-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-01-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-04-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-06-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-09-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	27-09-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-11-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-12-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-12-2020
Application type:	Amendment
Review commission:	METC NedMec

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	NL63162.031.17