Onderzoek naar kwaliteit van leven en zorggebruik bij gevorderde prostaat kanker

No registrations found.

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

Summary

ID

NL-OMON27164

Source
Nationaal Trial Register

Brief title
PRO-CAPRI

Health condition

Castration-resistant prostate cancer

Sponsors and support

Primary sponsor: sponsor Erasmus University Rotterdam, Institute for Medical Technology Assessment address PO Box 1738 postal code 3000 DR city Rotterdam country The Netherlands phone +31 10 408 8696 fax email office.hta@eshpm.eur.nl
Source(s) of monetary or material Support: ZonMw; project number 836011017

Intervention

Outcome measures

Primary outcome

To determine the HRQOL at baseline and changes over time during CRPC treatment

a. generic HRQOL by EQ VAS score and EQ-5D index value

b. cancer specific HRQOL by EORTC QLQ-C30 score

c. prostate cancer specific HRQOL by EORTC QLQ-PR25 score

Secondary outcome

To determine
a. indirect non-medical costs during CRPC treatment (productivity losses due to absenteeism)
b. direct medical costs outside the hospital during CRPC treatment (medical resource use outside the hospital and informal care)
c. self-reported pain by BPI-SF pain severity and interference

Study description

Background summary

Background of the study:
The annual incidence of castration-resistant prostate cancer (CRPC) in the Netherlands is estimated at 2868 patients. After development of CRPC, survival with best supportive care is not expected to exceed 12 months. Cancer has a great impact on health related quality of life (HRQOL). Fortunately, several new treatments for CRPC have been registered. These treatments have a palliative nature, comparable survival benefits and considerable costs. Especially when survival benefits are comparable, patient reported outcomes are essential to optimize patient selection for treatment in the general medical oncology practice. Moreover, patient reported outcomes are essential for economic evaluations. This study will provide knowledge of HRQOL outcomes and indirect costs in the daily practice of CRPC treatment. These outcomes will help patients and clinicians in clinical decision making, to determine optimal treatment strategies and guide future development of guidelines, from both a clinical and economical perspective.

Objective of the study: The objectives are to determine generic, cancer-generic and prostate cancer-specific HRQOL and costs outside the hospital in CRPC patients during treatment (including best supportive care, docetaxel, cabazitaxel, abiraterone and enzalutamide) in daily practice.

Study design: PRO-CAPRI is a prospective, observational, multi-center, cohort side study of the CAstration-resistant Prostate cancer RegIstry (CAPRI), an observational study in the Netherlands (NL3440). In September 2012, the observational CAPRI registry has been started. Clinical and economical outcomes are registered from 3600 CRPC patients, retrospectively included since 01-01-2010 in 20 hospitals from the Netherlands. The CAPRI and PRO-CAPRI outcomes will be combined for analysis.

Study population: A sample of the CAPRI population (CRPC patients). In 10 CAPRI hospitals, all CRPC patients will be identified and checked for eligibility. Newly diagnosed CRPC patients and patients starting a post-docetaxel treatment line are eligible. Informed consent is an inclusion criterium, and patients must be able to complete the questionnaires. A total of 200 patients will be included, and followed over time.

Primary study parameters/outcome of the study:
to determine the HRQOL at baseline and changes over time during CRPC treatment a. generic HRQOL by EQ VAS score and EQ-5D index value b. cancer specific HRQOL by EORTC QLQ-C30 score c. prostate cancer specific HRQOL by EORTC QLQ-PR25 score

Secundary study parameters/outcome of the study (if applicable): to determine a. indirect non-medical costs during CRPC treatment (productivity losses due to absenteeism) b. direct medical costs outside the hospital during CRPC treatment (medical resource use outside the hospital and informal care), and c. self-reported pain by BPI-SF pain severity and interference

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable): Since the only intervention is a self-administered questionnaire, risks are negligible. The questionnaires take approximately 30 minutes to complete. Every three months the questionnaires will be repeated.

Study objective

The annual incidence of castration-resistant prostate cancer (CRPC) in the Netherlands is estimated at 2868 patients. After development of CRPC, survival with best supportive care is not expected to exceed 12 months. Cancer has a great impact on
health related quality of life (HRQOL). Fortunately, several new treatments for CRPC have been registered. These treatments have a palliative nature, comparable survival benefits and considerable costs. Especially when survival benefits are comparable, patient reported outcomes are essential to optimize patient selection for treatment in the general medical oncology practice. Moreover, patient reported outcomes are essential for economic evaluations. This study will provide knowledge of HRQOL outcomes and indirect costs in the daily practice of CRPC treatment. These outcomes will help patients and clinicians in clinical decision making, to determine optimal treatment strategies and guide future development of guidelines, from both a clinical and economical perspective.

Study design

t=0,3,6,9,12,15,18,21,24 months

Intervention

Repeated HRQOL and cost assessment by questionnaires (EQ-5D, QLQ-C30, QLQ-PR25, BPI-SF and a selection of iMTA cost questionnaires every three months, starting at baseline.

Contacts

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Eligibility criteria

Inclusion criteria

Two populations are eligible for inclusion:

1. Patients newly diagnosed with CRPC. CRPC is defined by either the treating doctor/physician, or by the definition (prostate cancer that is progressing despite medical or surgical castration (i.e. castrate levels of testosterone (¡Ü 50 ng/dL or <1,7 nmol/L). If no testosterone has been measured, treatment with surgical castration or medical castration (LHRH-agonists or ¨Cantagonists) has to be initiated prior to progression of prostate cancer. Because anti-androgen withdrawal response may occur in patients treated with combined androgen blockade (medical or surgical castration plus continuous anti-androgen), progression must be evaluated after discontinuation of anti-androgens for 4 to 8 weeks. Progression is defined as either
progression according to the treating doctor/physician; or PSA progression, that is two rising PSA values at a minimum of 1-week intervals with a minimum starting value of 2,0 ng/ml; or radiologic progression, that is the appearance of two or more new lesions on bone scintigraphy or measurable disease (local or nodal or visceral progression)).

2. Patients diagnosed with CRPC after 1-1-2010 and now start the first post-docetaxel treatment line.

The time window for inclusion is three months from the diagnosis of CRPC, and three weeks before and three weeks after the start of the first second-line treatment after docetaxel.

Informed consent and the ability to complete the questionnaires are additional inclusion criteria.

Exclusion criteria

N/A

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2013
Enrollment:	200
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	30-07-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44771
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3934
NTR-old	NTR4096
CCMO	NL44602.029.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON44771

Study results

Summary results
M Kuppen, H Westgeest, A Van den Eertwegh, R Van Moorselaar, N Mehra, J Coenen, I Van Oort, A Van den Bergh, K Aben, D Somford, J Lavalaye, W Gerritsen, C Uyl-de Groot; Patient reported outcomes in the castration resistant prostate cancer registry (PRO-CAPRI). PCN388, 21th Annual European Congress ISPOR Barcelona, 2018.

Kuppen M, Westgeest H, Van Den Eertwegh A, Coenen J, Van Moorselaar R, Van Den Berg P, Geenen M, Mehra N, Hendriks M, Lampe M, Van De Luijtgaarden A, Peters F, Roeleveld T, Smilde T, De Wit R, Van Oort I, Gerritsen W, Uyl-De Groot C; Health-related Quality of Life and Pain in a Real-world Castration-resistant Prostate Cancer Population: Results From the PRO-CAPRI Study in the Netherlands. Clin Genitourin Cancer 2019 Dec 5. pii: S1558-7673(19)30366-0. doi: 10.1016/j.clgc.2019.11.015. [Epub ahead of print]